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The similarities and differences between distortion-product otoacoustic emission testing instruments and accuracy settings

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A thesis submitted in partial fulfillment of the requirements for the Master of Science degree in Health and Rehabilitation Sciences

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Abstract

Advanced measures of the auditory system like otoacoustic emission (OAE) testing are essential for highlighting the subtle expressions of hearing loss if clinical care is to remain up to date with current scientific knowledge. The purpose of this study was to compare distortion product OAE (DPOAE) testing across three different measurement systems (Interacoustic Titan, Bio-logic Scout and Vivosonic Integrity) to determine if there are differences in DPOAE testing. Secondly, the study will look to evaluate the effect if varying accuracy settings on DPOAE testing within the Integrity system. DPOAE tests evaluating levels, noise floor levels, probe fit check time and testing time across test frequencies from 2000 to 8000 Hz were compared in a total of twenty normal hearing adult. Findings show that DPOAE results are within normal limits across all devices and protocols. These findings allow audiologist to make more informed decisions when testing OAEs.

Keywords

Otoacoustic emission (OAE), Distortion product otoacoustic emission (DPOAE), DPOAE level, noise floor level, signal-to-noise ratio (SNR), probe fit, accuracy, test time, Titan, Scout, Integrity

Summary for Lay Audience

Advanced measures of the auditory system like otoacoustic emission (OAE) testing are essential for highlighting the subtle expressions of hearing loss if clinical care is to remain up to date with current scientific knowledge. This objective test which can reveal the health of

the cochlea is measured using specialized OAE measurement systems that allow audiologists to understand the underlying nature of possible hearing pathologies. However, advancements in software and hardware over the years has led to the development of many different OAE measurement systems from different manufacturers. With so many different systems now in existence, there is a lack in literature comparing the different devices in their performance. It remains unclear as to whether these systems can accurately conduct an OAE test despite using different software and hardware. Therefore, the proposed project will look to compare distortion product OAE (DPOAE) testing across three different measurement systems (Interacoustic Titan, Bio-logic Scout and Vivosonic Integrity) to determine if there are differences in DPOAE testing. Secondly, the study will look to evaluate the effect of varying accuracy settings on DPOAE testing within the Integrity system.

DPOAE tests evaluating levels, noise floor levels, probe fit check time and testing time across test frequencies from 2000 to 8000 Hz were compared in a total of twenty normal hearing adult. Results demonstrated that DPOAE levels were consistent across all three measurement systems and accuracy settings. However, differences in noise floor level, probe fit check time and test times were reported between instruments which suggest differences in averaging algorithms. Differences in noise floor level and test time estimates for varying accuracy settings in the Integrity were also reported, with the more accurate protocol yielding lower noise floor estimates yet longer test times compared to the fast (less accurate) protocol. This suggests that there is utility in varying accuracy settings depending on what an audiologist wants to evaluate and the testing circumstances. Given these findings, audiologists can now make a more informed decision when choosing what OAE measurement system to utilize and can rest assured that they will accurately conduct a DPOAE test.

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List of Abbreviations

American Speech Language and Hearing Association	ASHA
College of Audiologist and Speech-Language Pathologists of Ontario	CASLPO
Cubic centimeter	cc
Decapascal	daPa
Decibel	dB
Distortion Product Otoacoustic Emissions	DPOAE
Eta-Squared	η^2
Food and Drug Administration	FDA
Frequency of tone 1	f1
Frequency of tone 2	f2
Hertz	Hz
Infant Hearing Program	IHP
Infection Prevention and Control	IPAC
Inner hair cells	IHC
Kilohertz	kHz
Level of tone 1	L1
Level of tone 2	L2
Otoacoustic emissions	OAE
Outer hair cells	OHC

Repeated measures analysis of variance	RMANOVA
Signal to Noise Ratio	SNR
Sound Pressure Level	SPL
Standard Deviation	SD
Transient Evoked Otoacoustic Emissions	TEOAE

Chapter 1

1 Introduction

Otoacoustic emission (OAE) testing comprises one component of the audiological diagnostic test battery that can be used to indicate different audiological pathologies, monitor the effects of prescribed treatments and provide recommendations in the selection of hearing aids and other surgical options (Kemp, 2002). OAE testing is a non-invasive objective measure that requires minimal active participation from the listener. This allows them to be used with populations that are often difficult to test such as young children (Geal-Dor et al., 2010). Because of their reliability and utility, OAEs are now mandated to be used with newborns in an initiative to identify early hearing loss and other differential audiological diagnoses. However, advances in technology since the discovery of OAEs led to the development of different OAE measurement systems from different manufacturers, each boasting superiority. With so many different systems now saturating the OAE testing market and a lack of literature comparing these systems, it is largely unknown to many researchers and clinicians what system to use.

1.1 Otoacoustic Emissions

1.1.1 Generation of Otoacoustic Emissions

OAEs are produced by outer hair cells (OHCs) located within the cochlea. When recorded in the ear canal, they can be employed as objective measures used to evaluate aspects of the ear. Once sound waves reach the ear, vibrations of the tympanic membrane occur due to the varying sound pressure of the waves. The oscillation of the tympanic membrane varies depending on the incoming sound pressure levels (SPL). In the mid hearing frequency range of 1 to 5 kHz, a normal hearing adult can detect SPL at the hearing threshold of roughly 0 dB SPL, leading to tympanic vibration of less than 10 picometers (Gebeshuber, 2000). On the other hand, sounds at conversational speech levels (40 - 60 dB SPL) have been shown to produce movements 10-100 times larger (Chang et al., 2013). These movements are then conducted by the middle ear ossicles (malleus, incus, and stapes) to the oval window of the cochlea in the inner ear. The auditory ossicles are

fundamental for the transmission of sound energy. The auditory ossicles allow the impedance matching of sound travelling through the air to the fluid filled cochlea. The resulting energy transmitted via the ossicular chain causes movements along the basilar membrane of the inner ear, and of the cochlea's sensory hair cells, which include the inner and outer hair cells (IHCs, OHCs). The generation of OAEs reflect activity of OHCs along different areas of the basilar membrane, each representing a different characteristic frequency place within the human hearing range of 20 – 20,000 Hz.

This OAE generation relies on the cochlear amplifier, a positive feedback system that amplifies the vibrations within the inner ear in response to inputs to allow for their detection. Studies investigating the mechanisms underlying the cochlear amplifier have posited that the force driving the amplification process depends on the OHCs (Ashmore et al., 2010). Movements of the hair cells' stereocilia causes the opening and closing of ion receptors of the OHCs which causes shifts of intracellular voltage. Aside from inducing the process of depolarization, the voltage change has been linked to altering the electromotility of the OHCs, a process in which the length of the OHCs change in response to an electrical stimulation (Brownell, 1990). The changes in OHCs length depends on the motor protein prestin (Dallos et al., 2000).

Gene knock-out studies involving the deletion of the prestin gene were conducted on mice to show the effects of prestin in altering OHC length (Gao et al., 2002). Results of the study emphasized the effects prestin has on auditory brainstem response and distortion product otoacoustic emissions (DPOAEs). It was shown that lack of prestin in mice resulted in a decrease in cochlear sensitivity in a frequency-dependent manner due to impaired OHC electromotility. Further studies surrounding the function of prestin in hearing have sought to evaluate the regulation and expression of prestin when noise-induced hearing loss has occurred (Xia et al., 2013). Using mice who had undergone noise exposure protocols that resulted in a significant loss of OHCs and IHCs, the functional expression of prestin was evaluated and found to increase to partially compensate for the reduced force production due to missing OHCs. On the other hand, when compared to mice who had undergone a control with no OHC loss, it was found that the normal cochlear mechanisms typically in place were enough to maintain stable auditory thresholds.

Together, these studies highlight how the motor protein prestin is essential for OHC movement and thus hearing.

The energy produced by the moving OHCs is then propagated backwards through the middle ear to radiate by the tympanic membrane into the ear canal and produce OAEs. OAEs indicate peripheral auditory status which includes the outer, middle and inner ear functionality (Nozza, 2001). For instance, if one of these mechanisms along the pathway in which sound is propagated was impaired due to hearing diseases like otosclerosis, which would impede the middle ear due to abnormal bone growth, the outgoing OAE may be affected. The outgoing energy is then recorded (and reported in dB SPL) using a small fitted microphone placed within the ear canal.

1.1.2 Evaluating Otoacoustic Emissions

To evaluate OAE measurements, examination of OAE levels, noise floor, signal-to-noise ratio (SNR) and test time at key frequencies within a tested range are required. When conducting an OAE test, the SNR demonstrates the difference between the measured OAE emissions produced by the OHCs and the background noise level. Positive SNR values of at least 3 or 6 dB being are indicative of reliable OHC function. If the noise floor within a recording were elevated due to factors such as a high background room noise, or internal noise such as breathing and movement, the difference between recorded OAE level and noise level becomes smaller, resulting in a lower recorded SNR (Nassiri et al., 2016). As OAEs are vulnerable to even the smallest amount of background noise, having a high SNR criterion ensures that changes in OAE measurements are due to inner ear influences as opposed to external noise factors (Backus, 2007). This principle can be seen across varying studies utilizing OAEs. For instance, research looking into evaluating auditory efferent system function using OAEs have specified SNRs greater than 6 dB (Backus & Guinan, 2007; Mishra & Lutman, 2013).

1.1.3 Types of Otoacoustic Emissions

OAE responses will differ depending on the stimulus used to elicit them. Each different OAE type has its own benefits and weaknesses. Stimulus-frequency OAEs (SFOAEs) occur at the same frequency and time that a continuous pure tone is applied to an ear. To

detect and extract them, SFOAEs must be dissociated from the pure tone stimulus. This involves exploiting the nonlinear nature of SFOAE level (Dunckley, 2016). Past research has shown that SFOAEs grow linearly in response to low level stimuli while at high stimulus levels, SFOAEs show patterns of saturation. Therefore, the net sound measured at these high levels in the ear canal can be separated into stimulus and response components (Neely et al., 2005). Because SFOAEs require a single probe tone, they are regarded as being frequency specific and more easily understood compared to other emissions. However, they have been reported to be poorly correlated with behavioural thresholds and yield poorer SNR at higher frequencies and are thus, not conventionally used in audiological tests (Ellison & Keefe, 2005).

Distortion-product OAEs (DPOAEs) on the other hand are widely used, especially to screen for hearing loss in newborns (Bagatto et al., 2019). DPOAEs originate due to the nonlinearity of a healthy ear. The non-linear aspect of the ear, specifically the cochlear amplifier introduced above, allows for a large dynamic range in hearing. However, the nonlinearity also introduces new energy at frequencies other than those of the input stimulus which are referred to as distortions. DPOAEs are elicited by presenting two primary tone stimuli of different frequencies (f_1 and f_2) and levels (L_1 and L_2) at the same time where f_2 is greater than f_1 , while L_1 is greater than L_2 . If f_1 and f_2 are close in frequency, interaction of these frequencies result in output of energy at other frequencies in the cochlea referred to as intermodulation distortion (Zelle et al., 2017). DPOAEs are these intermodulation distortions that are transmitted through the middle ear and are then measured in the ear canal.

DPOAEs occur at predictable frequencies that depend on the frequency and magnitude of f_1 and f_2 . The DPOAE $2f_1 - f_2$ is the largest of the DPOAEs in humans and is often most investigated at a L_1/L_2 ratio of 65/55 dB SPL as it rapidly provides robust and clinically viable information about the function of the cochlear amplifier (Fitzgerald & Prieve, 2005). The further apart the primary frequencies, the smaller their interactions and the smaller the DPOAEs. Common DPOAE functions show a growth with level followed by a saturation. These points of saturation vary across individual ears and can be used to define normal hearing versus hearing impairments (Marcrum et al., 2016). Despite being more complex

in nature, DPOAEs are able to test a wide frequency range. This has led to their extensive investigation and the establishment of DPOAE testing protocols and normative data (Gorga et al., 1997; Ramos, 2013).

Another widely used OAE measurement is that of transient evoked OAEs (TEOAEs). Elicited with a click stimulus or a tone-burst and typically used for testing newborns and young children. TEOAEs are only present in ears with normal cochlear and middle ear function. They are absent or reduced in ears with even a mild degree of loss (Meena et al., 2013). Therefore, they provide great utility in detecting cochlear dysfunction in a frequency specific manner. However, TEOAEs measured in normal hearing adults have been shown to provide weaker responses relative to DPOAEs at higher frequencies (Ibargüen et al., 2008). Despite TEOAEs having greater effectiveness at testing lower frequencies compared to DPOAE testing, they do not offer a wide frequency range for observation. Therefore, for the purpose of this study, DPOAEs will be selected as the primary stimulus for the comparison of different OAE measurement systems.

1.2 Need for the study

Since the conception of newborn hearing screening programs, the number of systems now capable of conducting DPOAE screening have increased. Although studies exist evaluating the individual performance of these systems and their utility in assessing different cohorts of the population, there is no quantifiable evidence to suggest how they may perform in a side-by side comparison. It is important in audiology for patients tested in different locations, using different equipment, to produce comparable results. This requires assessment of the clinical tools available as well as adherence to strict testing protocol. The last study comparing Food and Drug Administration (FDA) approved DPOAE devices was conducted in 2001. There exists a need to quantify the performance of current technology to determine their similarities and differences with current test protocols (Parthasarathy & Klostermann, 2001).

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Chapter 2

2 OAE Standardization Testing Protocol Development

To objectively compare OAE measurement systems, a standard test protocol must be used across all devices. The OAE standardized test protocol that was used in this study was based on the pre-existing Ontario Infant Hearing Program (IHP) OAE screening protocol (Bagatto et al., 2020). The IHP program is one of many early hearing detection and intervention programs and seeks to minimize the effect of hearing loss on a child's development (Bagatto et al., 2019). The most recent IHP protocol for conducting a DPOAE screening test utilizes the Vivosonic Integrity system. This protocol specifies testing the frequencies of 1000, 2000, 3000 and 4000 Hz in descending order with detection criteria that include having a cut-off SNR of 8 dB and a minimum DP amplitude of -5 dB SPL. The stimulus parameters include an F2/F1 ratio of 1.22, L1/L2 levels of 65/55 dB SPL, test using the "Fast" protocol and obtain agreement over two runs.

2.1 Modifications to DPOAE test protocol

Although suitable for young infants, utilizing the current IHP DPOAE test protocol on adults is inadequate and required modification. When examining the testing range of 1000 – 4000 Hz, it is known to not be fully representative the normal human auditory speech production range. Higher frequency sounds such as /s/ are produced at 7000 Hz and would be experienced daily by adults. Therefore, in order to fully evaluate the test performance of the varying devices, it would be logical to test what normal hearing adults perceive and as such, the proposed OAE comparison protocol was to test up to a maximum of 8000 Hz. However, the lower limit of 1000 Hz was omitted as OAEs at low frequencies are known to have higher noise estimates, thus yielding poor SNR. To minimize testing time during the ongoing Covid-19 pandemic, 1000 Hz and lower frequencies were excluded. Therefore, the comparison protocol tested the frequencies of 2000, 3000, 4000, 6000 and 8000 Hz in descending order. Secondly, OAE levels in adults have been shown to be significantly lower than infants. This can be attributed to developmental changes in the auditory system that would increase the level of ear canal recorded OAEs. Lastly, the DPOAE level pass criterion was set to 0 dB SPL instead of the IHP conventional -5 dB SPL. By setting stricter

pass criteria, make it possible to ensure that obtained DP levels are reflective of inner ear function and are not due to noise. The remaining properties of SNR, F1/F2 ratio, L1/L2 and number of runs remained consistent with the IHP protocol.

2.1.1 Calibration check of DPOAE measurement systems

Prior to the testing of participants, a verification check of the three measurement systems was performed to ensure they were properly calibrated. Disposable probe tips were attached to the various systems and individually, were attached at the reference plane of a 2cc coupler using putty to ensure a sealed fit. This apparatus was then placed inside a sound attenuated chamber while the OAE comparison protocol was executed. The recorded sound files were then analyzed in Praat (Boersma et al., 2021) to compare F1/F2 and L1/L2 ratios. Analysis revealed that the three OAE measurement systems were nominally calibrated equally, but it was not possible to exactly compare relative levels within tone pairs. Due to differing probe tip calibration procedures among the three systems, the L1/L2 levels detected varied for different tone pair frequencies and across instruments as seen in Figure 1. However, the level at the OAE probe tip was estimated during measurements by each instrument to be the desired L1/L2 level of 65/55 dB SPL. Note that the expected results from the calibration estimate are for levels to be approximately L1 (65 dB SPL) as the influence of L2 (55 dB SPL) should not affect this value due to the expected 10 dB SPL difference between the tone pairs.

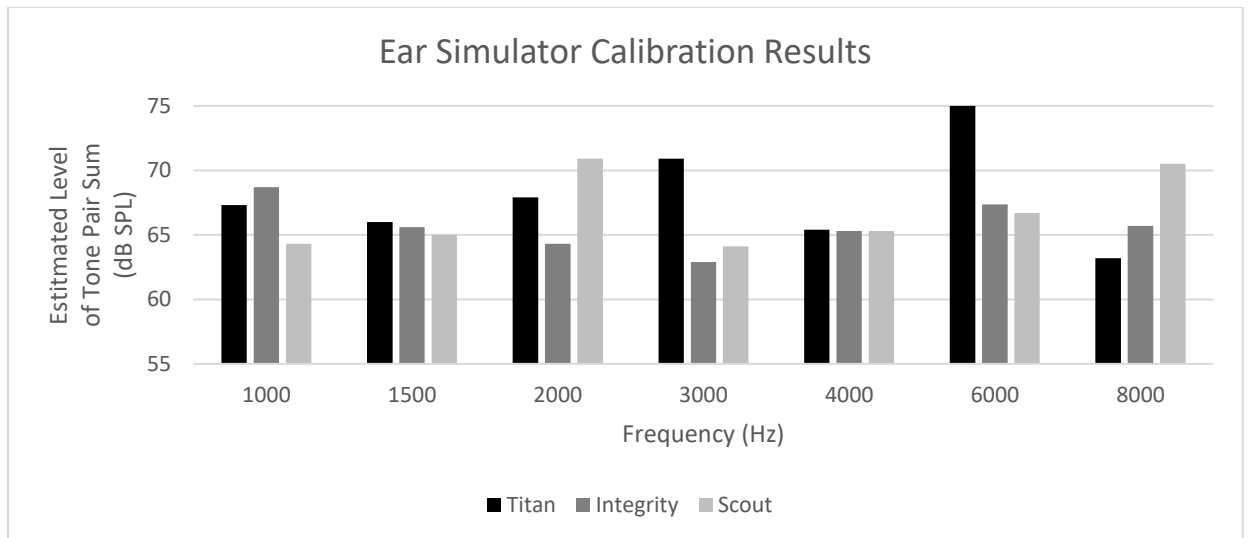


Figure 1. DPOAE stimulus recordings conducted from 1000 Hz – 8000 Hz for 3 DP systems. The results show the expected L1/L2 across all devices.

2.1.2 Purpose of the study

This study compares the DPOAE test performance of three different measurement systems using a modified IHP protocol and determine if there are any differences in DPOAE test performance. Within the Integrity system two available accuracy settings were assessed. It was hypothesized that all systems would yield similar OAE test results and that differences in accuracy settings would yield different OAE test results within the Integrity system.

2.1.3 Infection Prevention and Control Protocol for COVID-19

Due to the ongoing nature of the Covid-19 virus, the infection prevention and control protocol (IPAC) was developed at Western University to provide a safe environment within the testing facility. This includes the proper use of screening and scheduling, strict cleaning and disinfection procedures of equipment and high traffic areas, proper usage of personal protective equipment such as masks and face shields and other preventative measures.

2.2 Methods

2.2.1 Participants

Twenty young English-speaking adults with normal hearing from Western University (13 females, 7 males; age range: 18-25 years, mean: 23.6 years. SD: ± 1.0 years) were enrolled. Normal hearing of participants was established using a hearing screening test battery which included both a questionnaire and objective tests. Participants were asked to complete the International Organization for Standardization Questionnaire for hearing tests which is used to specify testing conditions for determining the hearing thresholds of subjects (ISO 389-9 – Annex A, 2009). Questions that were asked included background history regarding noise exposure and hearing health. Participants who were revealed to have a history of noise exposure or irregular hearing health history were followed up with a hearing evaluation which included objective tests of otoscopy, 226 Hz tympanometry (tympanometric gradient 50 – 110 daPa [ASHA, 1990]), acoustic admittance measures and reflex testing (≤ 90 dB [Gelfand, 2016]), and pure-tone audiometry testing 500 Hz – 8000 Hz (≤ 20 dB HL [ANSI, 1996]). Hearing evaluations were performed according to ASHA (2006) and CASLPO (2008) guidelines.

Due to the ongoing nature of the Covid-19 pandemic, recruitment of participants was strictly limited to Western graduate students from Elborn College in compliance with research ethics. IPAC procedures regarding proper sanitization and use of personal protective equipment were followed. This study was performed in the Child Hearing Research Laboratory of the NCA at the University of Western Ontario. Informed consent for participants was obtained in writing before the initiation of the evaluation.

2.2.2 Stimuli, Task and Procedures

DPOAE testing was conducted with three DPOAE measurement systems which control signal generation and presentation: Vivosonic's Integrity, Interacoustic's Titan, and Biologic's Scout. Stimuli were presented monaurally via each instrument's probe using individually sized disposable plastic tips. Testing parameters were established by modifying existing Ontario Infant Hearing Program protocols (Bagatto et al., 2020) to establish a consistent testing framework. This included DPOAE testing to be conducted at 2000, 3000, 4000, and 8000 Hz in descending order. Distortion product OAE level pass criterion was set to 0 dB SPL whereas SNR criterion was set to 8 dB. F1/F2 ratio was 1.22, L1/L2 levels were 65/55 dB SPL, and total test time per frequency was 15 s leading to a maximum measurement time of 75 s total for all DPOAE frequencies if required. These parameters were used across all three devices with only one difference in naming convention. Repeatability/accuracy of the measurement systems, which determines how long signals are averaged, were set to being equivalent across all devices. However, these settings are referred to as a "Fast" protocol on the Integrity and 95% accurate on the Titan and Scout.

For a second analysis evaluating two different protocols within the Integrity system, the "Accurate" setting was also compared with the "Fast" protocol of the Titan and Scout. While testing a stopwatch was used to record the elapsed test time. This time was broken down to two components, probe check time which denotes activation of the program and probe fit check, and test time which starts once the probe fit check has been passed and ends after all frequencies have been tested. One descending run of the frequencies was considered a trial, with two trials being conducted per ear per system. To evaluate test-retest of subjects, the probe was removed and re-inserted between each trial. Figure 1 is an example of the process which a subject would undergo for each protocol in each ear. This would result in a total of 16 DPOAE trials being conducted per participant across the three systems. The systems and ears used in the study were counterbalanced to control for a potential order bias. Participants were seated inside a sound insulated booth and were instructed to remain quiet and relaxed while DPOAE testing occurred. DP levels, SNR

levels, noise floor levels, probe check time, and test time were collected across all three systems



Figure 2. Example of a set of protocols a subject would complete.

A repeated measures analysis of variance (RMANOVA) was used to evaluate group differences and effect sizes are reported as Eta-Squared (η^2). For all analyses, a significance level of $p < 0.05$ was chosen. The analysis was conducted in R and JASP. Post hoc analyses used Bonferroni corrections to adjust for multiple comparisons. For instances where Mauchly's test of sphericity was violated ($p < 0.05$), Greenhouse-Geisser sphericity corrections were applied.

2.3 Reference

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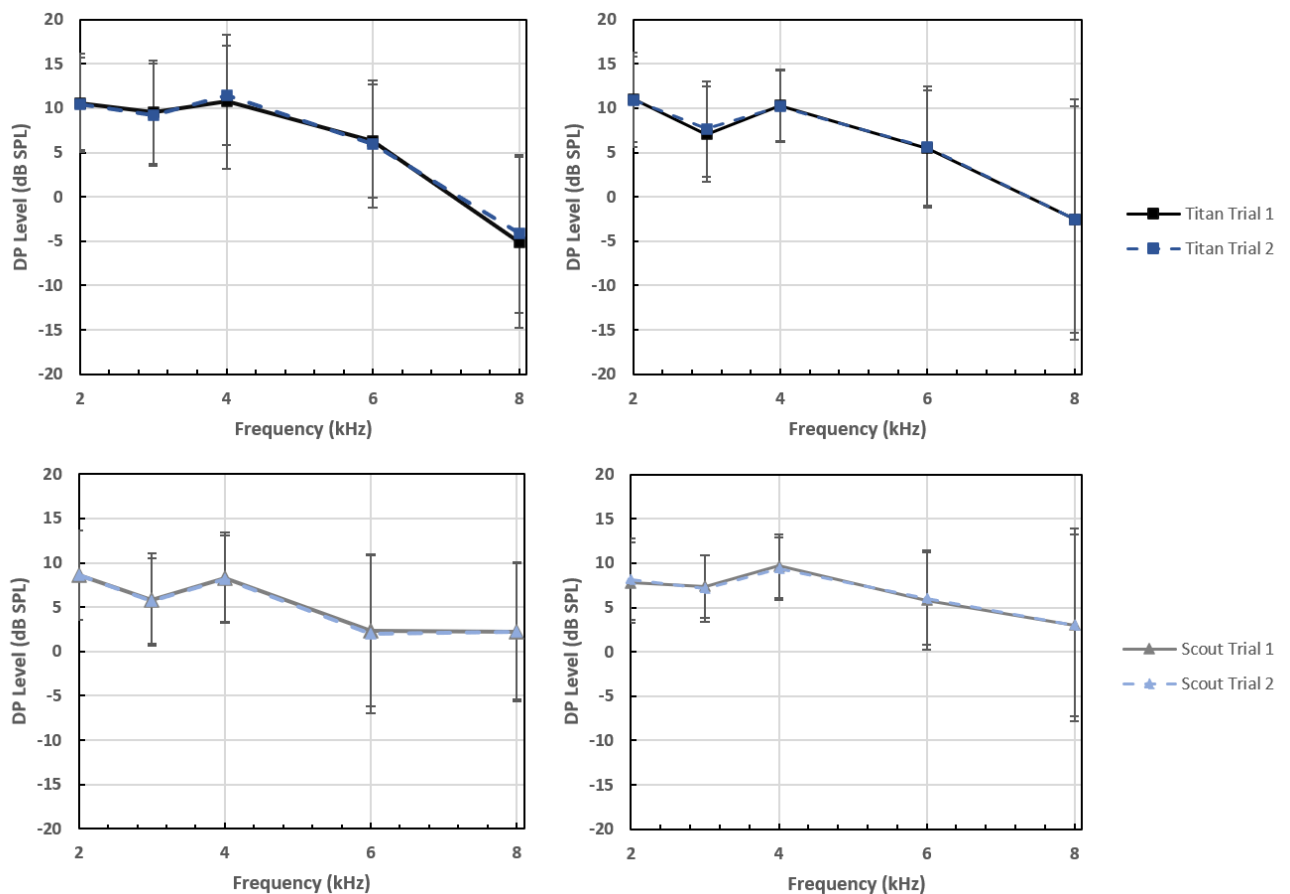
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Chapter 3

3 Results

3.1 DPOAE level comparison across three measurement systems

Figure 3 shows the mean DPOAE levels of young adults for the right and left ear across 3 different DPOAE measurement systems. Overall, mean DPOAE levels were consistent across all devices. Both Titan and Scout decreased in DPOAE level as frequency increases, with Titan showing the lowest DPOAE level at 8 kHz. Vivosonic Integrity DPOAE levels were similar across all frequencies.



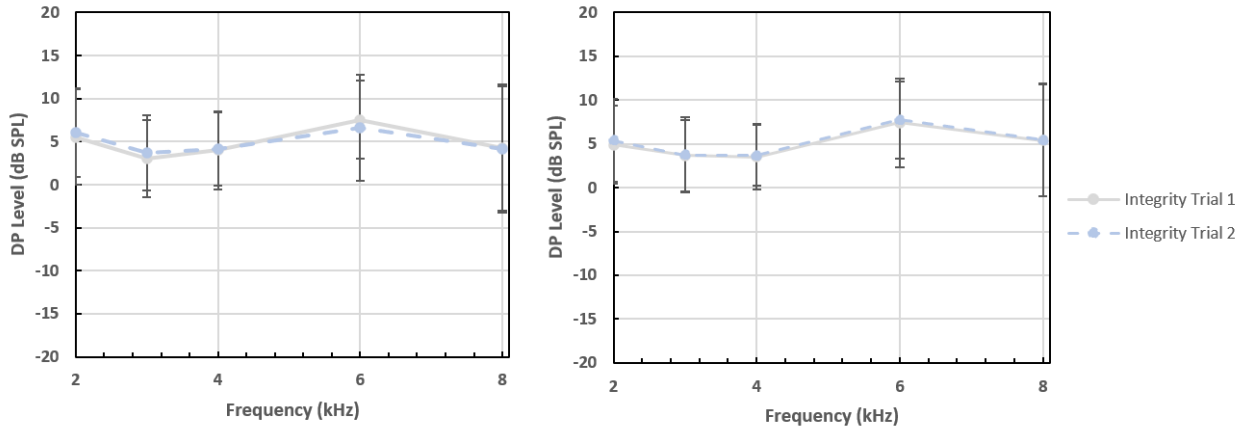


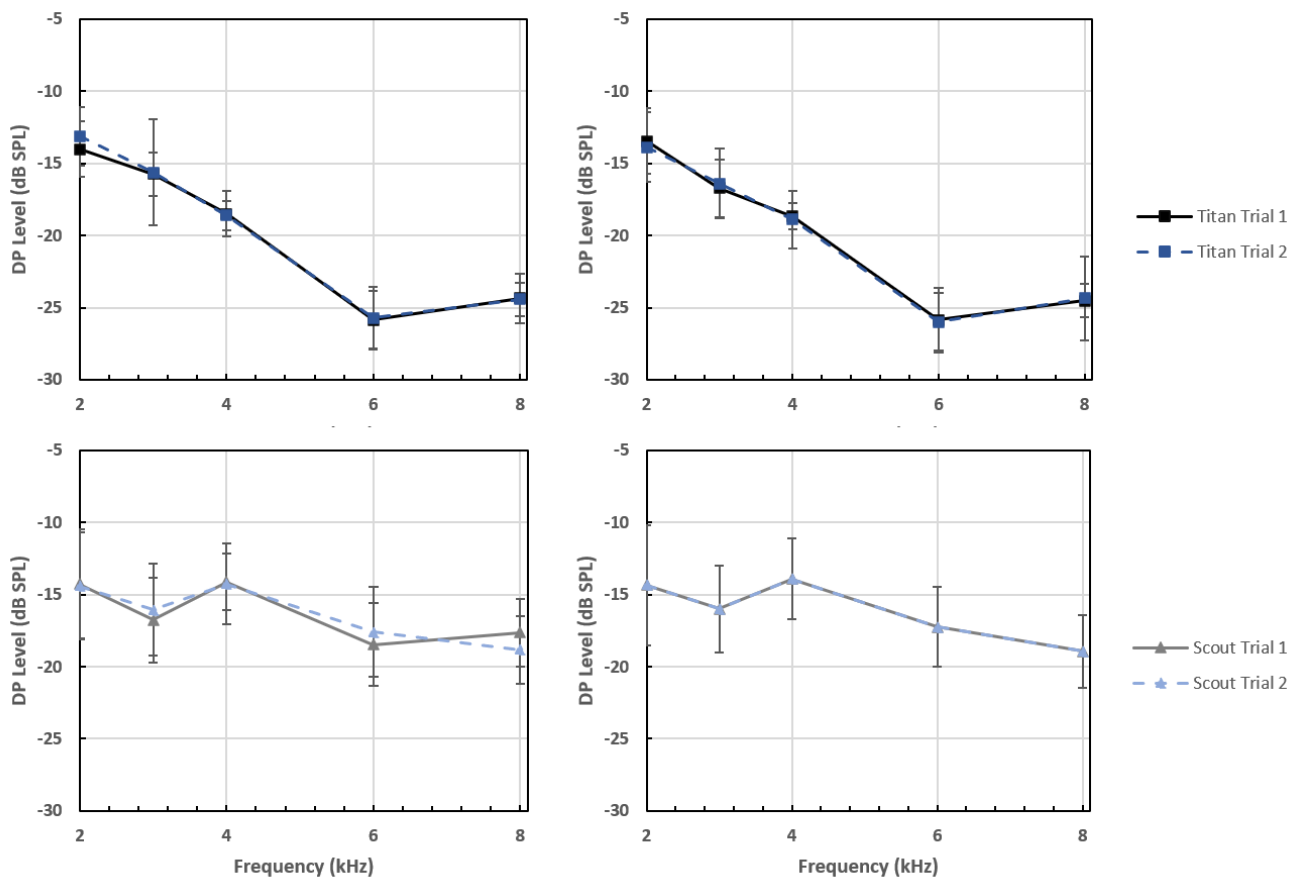
Figure 3. Averaged DPOAE Levels across three DPOAE systems for the right ear (left) and left ear (right) as a function of frequency. DPOAEs for trial one and trial two are shown. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on DPOAE levels with the ear (right and left), trials (1 and 2) and frequency (2000, 3000, 4000, 6000, and 8000 Hz) as within-subject factors and DPOAE measurement systems (Vivosonic Integrity, Interacoustic Titan and Bio-logic Scout) as the between-subject factor. Analysis of the data revealed no significant differences in DPOAE levels between DPOAE measurement systems [$F_{(2, 57)} = 0.565, p = 0.571, \eta^2 = 0.007$]. There was a significant interaction between frequency and machine [$F_{(3, 721, 106.055)} = 13.893, p < 0.001, \eta^2 = 0.113$]. Bonferroni post hoc t-tests were used to examine this interaction. Within the Titan, the DPOAE levels at 8 kHz were significantly lower when compared to its other test frequencies (2 kHz [$t_{(228)} = 11.331, p < 0.001$], 3 kHz [$t_{(228)} = 9.442, p < 0.001$], 4 kHz [$t_{(228)} = 11.265, p < 0.001$], and 6 kHz [$t_{(228)} = 7.434, p < 0.001$]). DPOAE levels at 6 kHz were also shown to be significantly lower when compared to DPOAE levels at test frequencies of 2 kHz [$t_{(228)} = 3.897, p = 0.013$] and 4 kHz [$t_{(228)} = 3.831, p = 0.017$]. DPOAE levels for the Scout were significantly lower at 8 kHz when compared to its DPOAE levels at 2 kHz [$t_{(228)} = 6.609, p < 0.001$] and 4 kHz [$t_{(228)} = 4.941, p < 0.001$]. The Scout DPOAE levels at 6 kHz were also significantly lower when compared to its 4 kHz [$t_{(228)} = 3.826, p = 0.018$]. There were no reported significant differences in DPOAE levels among the test frequencies for the Vivosonic Integrity ($p > 0.05$) and among other test frequencies in the Titan and Scout ($p > 0.05$). There were no significant differences between ears [$F_{(1, 57)} = 0.849, p = 0.361, \eta^2 = 9.373e^{-4}$] and for test re-test trials [$F_{(1, 57)} = 1.823, p = 0.182, \eta^2 = 2.917e^{-5}$]. There was no significant 4-way

interaction between Trials, Ears, Frequency or Machines [$F_{(8, 228)} = 0.740$, $p = 0.656$, $\eta^2 = 2.012e^{-4}$].

3.2 Noise floor comparison across three measurement systems

Figure 4 shows the mean noise floor levels for the right and left ear across three different DPOAE measurement systems. As can be seen from Figure 4, the mean noise floor levels for Vivosonic Integrity were elevated compared to the Scout and Titan. The mean noise floor of Vivosonic Integrity was shown to remain flat as the frequency increased, whereas the noise floor levels decreased for Interacoustic Titan and Bio-logic Scout.



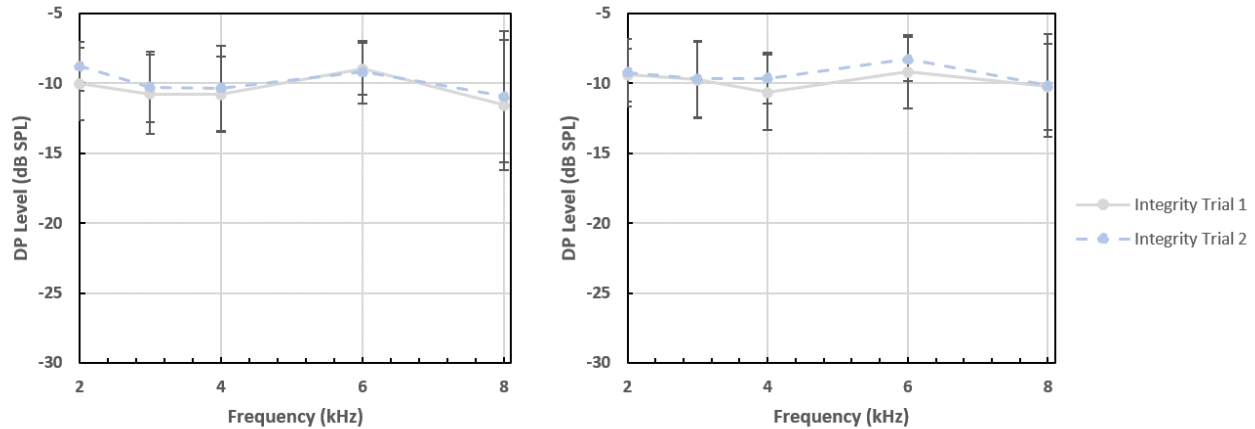


Figure 4. Averaged Noise Floor levels across three DPOAE systems for the right ear (left) and left ear (right) as a function of frequency. Noise levels for trial one and two are shown. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on noise levels with the ear (right and left), trial (1 and 2) and frequency (2000, 3000, 4000, 6000, and 8000 Hz) as within-subject factors and DPOAE measurement systems (Vivosonic Integrity, Interacoustic Titan and Bio-logic Scout) as the between-subject factor. Analysis of the data revealed significant differences in noise levels between DPOAE measurement systems [$F_{(2, 57)} = 247.625, p < 0.001, \eta^2 = 0.510$]. Noise floor average values for the Integrity are shown to remain flat across test frequencies, with an average of $-9.359 \text{ dB SPL} \pm 2.519 \text{ dB SPL}$ at 2000 Hz and an average of $-10.734 \text{ dB SPL} \pm 4.135 \text{ dB SPL}$ at 8000 Hz. On the other hand, the Titan and Scout show declining noise floor values as frequency increases, with an average of $-13.621 \text{ dB SPL} \pm 2.696 \text{ dB SPL}$ and $-14.34 \text{ dB SPL} \pm 4.073 \text{ dB SPL}$ at 2000 Hz respectively and averages of $-24.408 \text{ dB SPL} \pm 1.778 \text{ dB SPL}$ and $-18.585 \text{ dB SPL} \pm 2.496 \text{ dB SPL}$ at 8000 Hz respectively. There was a significant interaction between frequency and machine [$F_{(7.106, 202.513)} = 56.024, p < 0.001, \eta^2 = 0.130$]. Bonferroni post hoc t-tests were used to examine this interaction. For Titan, the noise floor levels at 8 kHz were significantly lower when compared to the test frequencies of 2 kHz [$t_{(228)} = 20.282, p < 0.001$], 3 kHz [$t_{(228)} = 15.593, p < 0.001$], and 4 kHz [$t_{(228)} = 10.798, p < 0.001$]. The noise floor levels at 6 kHz were significantly lower when compared to noise floor levels at 2 kHz [$t_{(228)} = 23.009, p < 0.001$], 3 kHz [$t_{(228)} = 18.320, p < 0.001$], and 4 kHz [$t_{(228)} = 13.525, p < 0.001$]. The noise floor levels at 4 kHz were significantly lower when compared to noise floor levels at 2 kHz

[$t_{(228)} = 9.484, p < 0.001$] and 3kHz [$t_{(228)} = 4.795, p < 0.001$], and the noise floor levels at 3 kHz were significant lower than the noise floor levels at 2 kHz [$t_{(228)} = 4.689, p < 0.001$]. However, the noise floor levels were not significantly different between 6 kHz and 8 kHz [$t_{(228)} = -2.727, p = 0.724$]. Examining noise floor levels at test frequencies in the Scout, levels at 8 kHz were significantly lower when compared to 2 kHz [$t_{(228)} = 7.982, p < 0.001$], 3 kHz [$t_{(228)} = 4.480, p = 0.001$], and 4 kHz [$t_{(228)} = 8.532, p < 0.001$]. Noise levels at 6 kHz were significantly lower compared to noise levels at 2 kHz [$t_{(228)} = 6.191, p < 0.001$] and 4 kHz [$t_{(228)} = 6.741, p < 0.001$]. Noise levels at 3 kHz were significantly lower than noise levels at 4 kHz [$t_{(228)} = -4.052, p = 0.007$]. There were no significant differences between ears [$F_{(1, 57)} = 0.648, p = 0.424, \eta^2 = 1.442e^{-4}$] and for test re-test [$F_{(1, 57)} = 1.935, p = 0.170, \eta^2 = 2.788e^{-4}$]. There was no significant 4-way interaction between Trials, Ears, Frequency or Machines [$F_{(8, 228)} = 1.435, p = 0.183, \eta^2 = 6.992e^{-4}$].

3.3 Probe check time comparison across three measurement systems

In Figure 5, the mean probe check time of the three DPOAE measurement systems across two different trials is plotted. Figure 5 shows that the mean probe check time of the Titan is shorter compared to Vivosonic Integrity and the Scout.

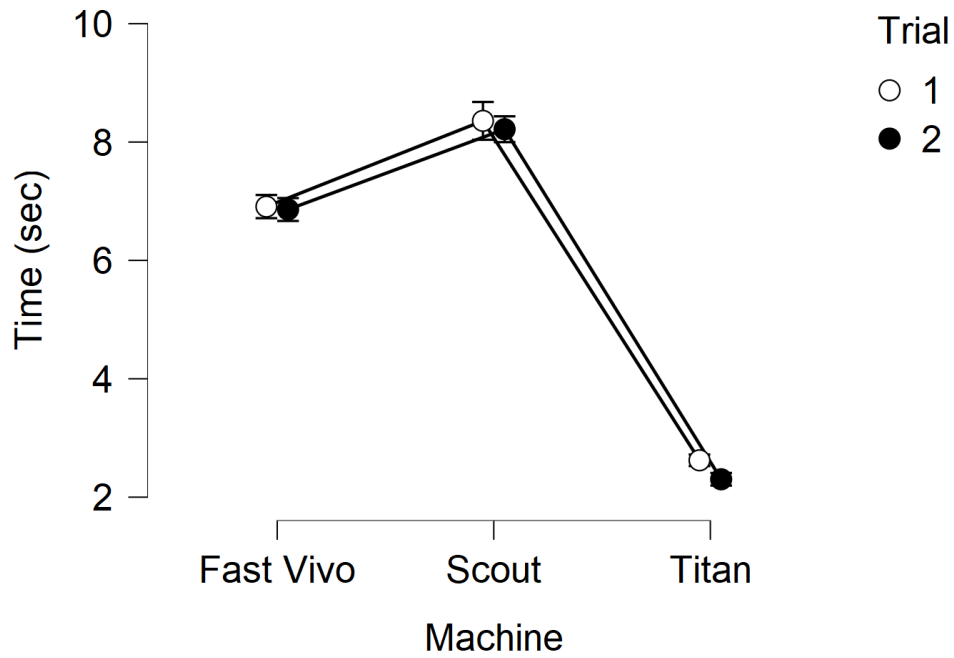
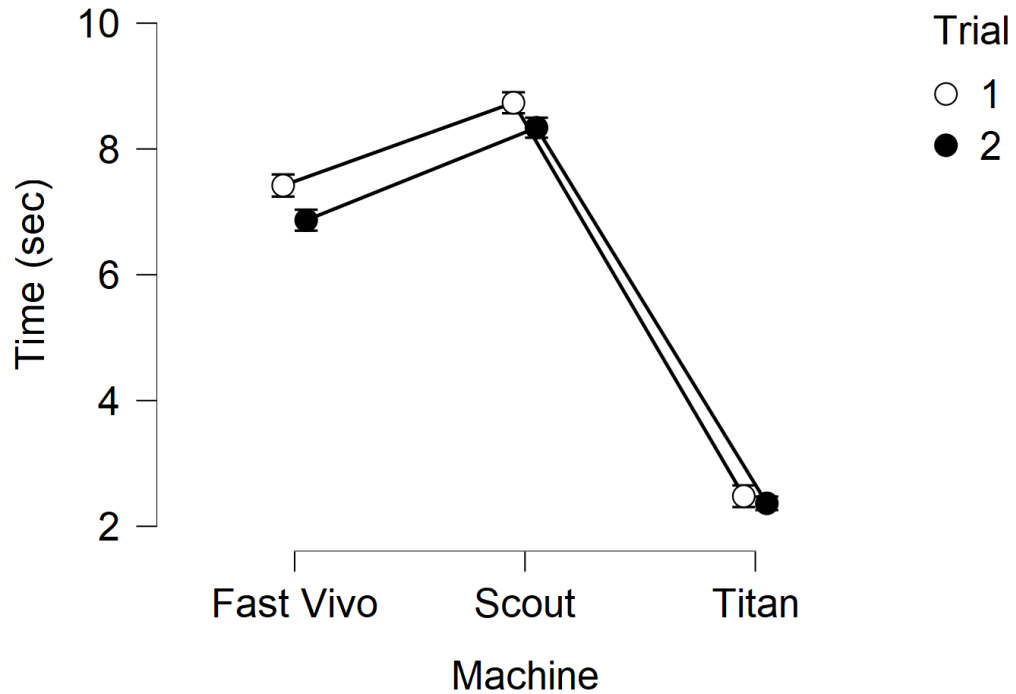
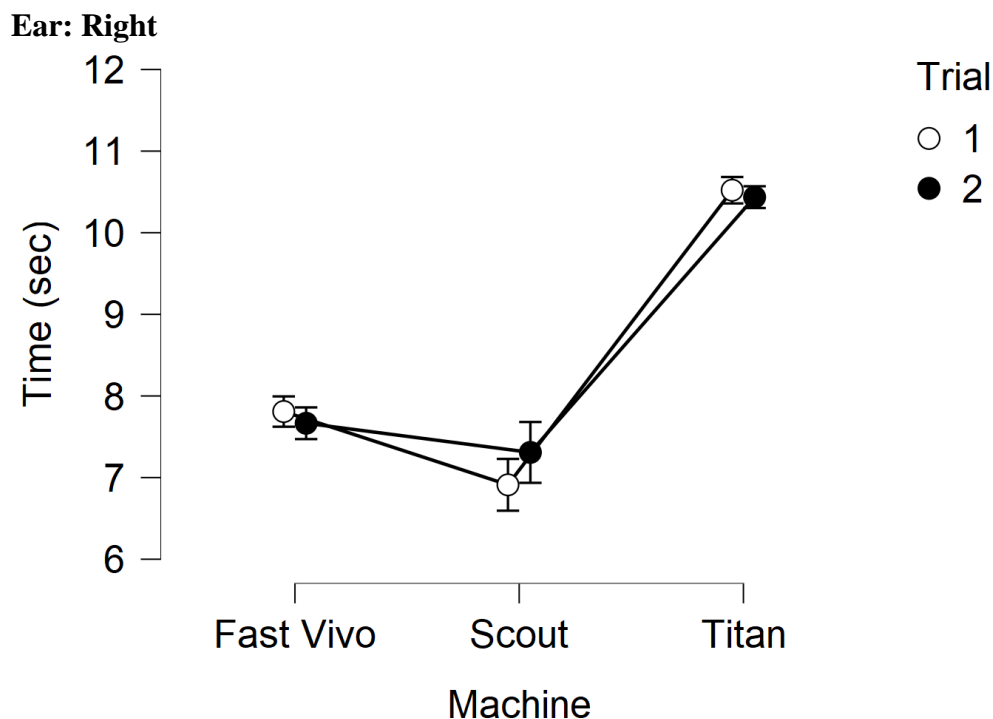
Ear: Right**Ear: Left**

Figure 5. Average probe check time (in seconds) across three DPOAE measurement systems for right and left ear. The white data points represent trial 1 and filled black data points represent trial 2. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on probe check time with the ear (right and left), and trial (1 and 2) as within-subject factors and DPOAE measurement systems (Vivosonic Integrity, Interacoustic Titan and Bio-logic Scout) as the between-subject factor. Analysis of the data revealed significant differences in probe check time between systems [$F_{(2, 57)} = 204.174$, $p < 0.001$, $\eta^2 = 0.821$]. Bonferroni post hoc t-test showed that the Integrity probe check time was significantly shorter compared to the Scout [$t_{(57)} = -4.524$, $p < 0.001$], but significantly longer than Titan's probe check time [$t_{(57)} = 14.794$, $p < 0.001$]. Comparing the probe check time of the Scout to Titan also reveals it to be significantly elevated [$t_{(57)} = 19.318$, $p < 0.001$]. There were no significant differences between ears [$F_{(1, 38)} = 2.742$, $p = 0.103$, $\eta^2 = 7.628e^{-4}$], trials [$F_{(1, 38)} = 4.360$, $p = 0.041$, $\eta^2 = 0.002$] and no significant within group interactions.

3.4 Test time comparison across three measurement systems

Figure 6 shows the mean test time of young adults for the right and left ear across 3 different DPOAE measurement systems. As can be seen from Figure 6, the mean test time for Titan was elevated compared to the Scout and Integrity systems.



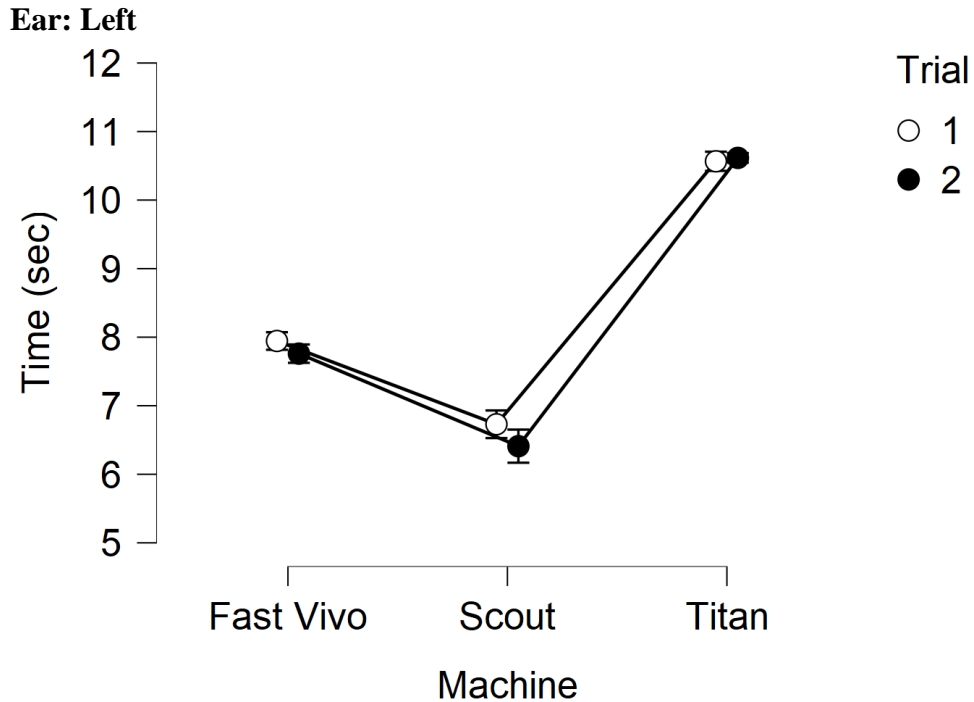


Figure 6. Average test time (in seconds) across three DPOAE measurement systems for right and left ear. Error bars around the mean represent +/- 1 standard deviation.

A RMANOVA was carried out on test time with the ear (right and left), and trial (1 and 2) as within-subject factors and DPOAE measurement systems (Vivosonic Integrity, Interacoustic Titan and Bio-logic Scout) as the between-subject factor. Analysis of the data revealed significant differences in total test duration between systems [$F_{(2, 57)} = 149.446$, $p < 0.001$, $\eta^2 = 0.687$]. Bonferroni post hoc t-tests showed that the Integrity test time was significantly elevated compared to test time using the Scout [$t_{(57)} = 4.304$, $p < 0.001$] yet lower when compared to the test time of the Titan [$t_{(57)} = -12.349$, $p < 0.001$]. Comparing the test time of the Scout to the Titan also revealed the Scout to be significantly lower [$t_{(57)} = -16.653$, $p < 0.001$]. There were no significant differences between ears [$F_{(1, 57)} = 0.703$, $p = 0.405$, $\eta^2 = 7.623e^{-4}$], trials [$F_{(1, 57)} = 0.158$, $p = 0.692$, $\eta^2 = 1.591e^{-4}$] and other within group factors.

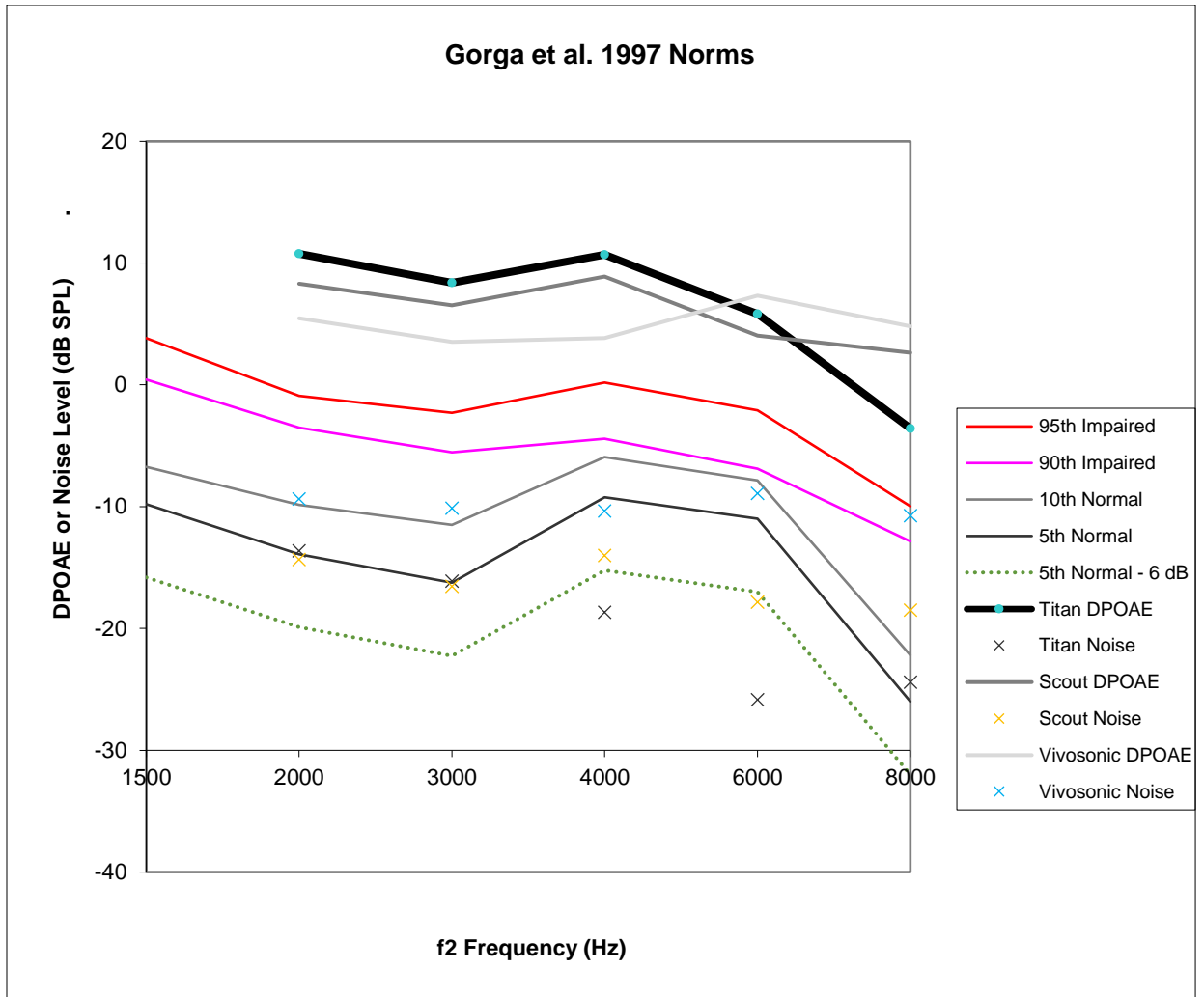


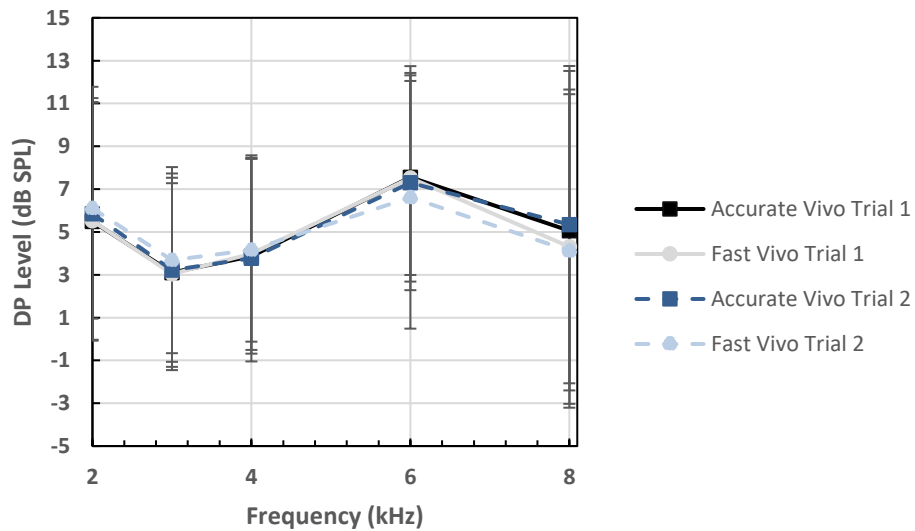
Figure 7. Results across all three measurement systems in comparison to DPOAE normative data

When results across all three measurement systems are compared to DPOAE normative data (Gorga et al., 1997), all DPOAE levels are above the 95th percentile of ears with hearing impairment, which is consistent with the hearing tests confirming that participants were of the normal hearing population. Average noise level as denoted by “x” markers are seen to vary substantially across devices in comparison to averaged DPOAE levels.

3.5 DPOAE level comparison between Vivosonic fast and accurate protocol

Figure 8 shows the mean DPOAE levels of young adults for the right and left ear between the Accurate and Fast collection settings in Vivosonic's Integrity. Overall, mean DPOAE levels were consistent between both protocols, with an increased averaged DPOAE level at 6 kHz across both ears.

Ear: Right



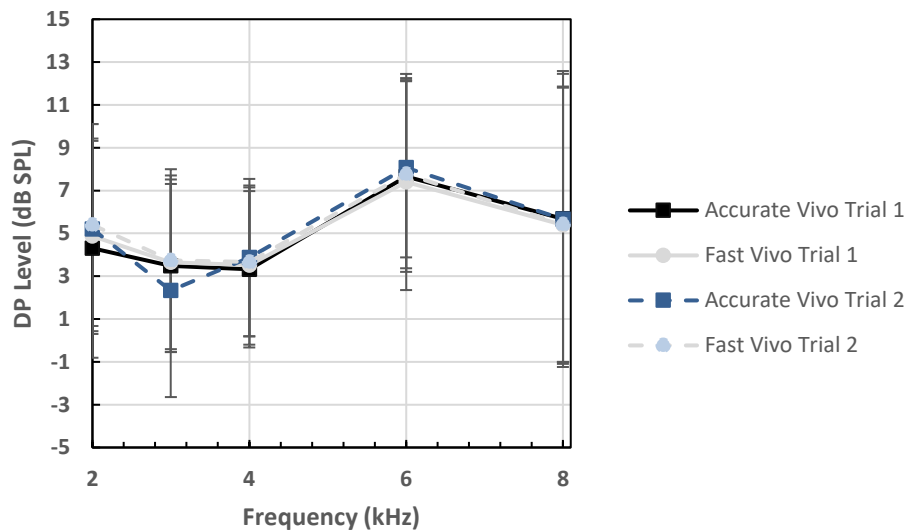
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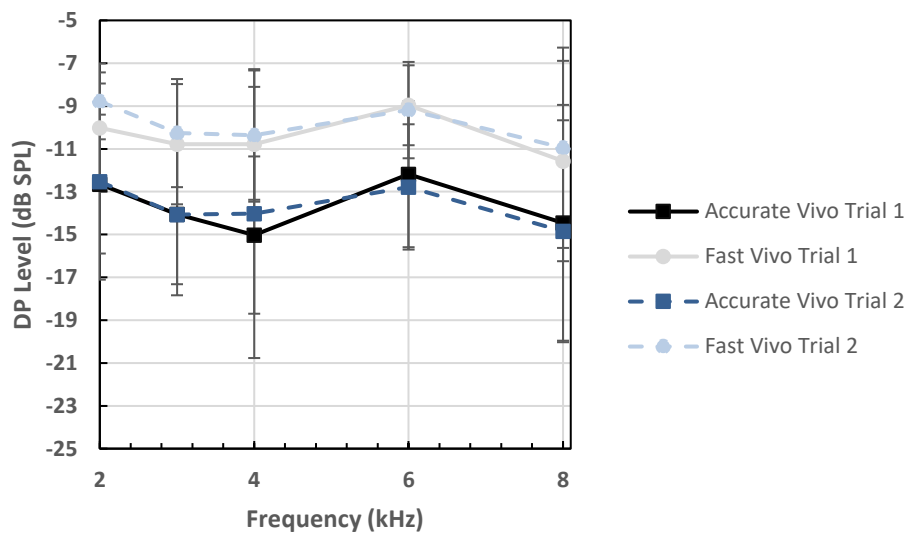
Figure 8. Average DPOAE Levels for Vivosonic Integrity's Fast and Accurate data collection protocols for the right and left ear as a function of frequency. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on DPOAE levels with the ear (right and left), trial (1 and 2) and frequency (2000, 3000, 4000, 6000, and 8000) as within-subject factors and DPOAE measurement protocols of the Integrity (Fast and Accurate) as the between-subject factor. Analysis of the data revealed no significant differences for the between subject factor [$F_{(1, 38)} = 0.0001374$, $p = 0.991$, $\eta^2 = 1.705e^{-6}$] implying that the DPOAE levels between both protocols were similar across frequencies. There was a significant difference in DPOAE levels across different test frequencies [$F_{(4, 152)} = 12.615$, $p < 0.001$, $\eta^2 = 0.073$]. Bonferroni post hoc t-tests showed that the DPOAE levels at 6 kHz were significantly elevated when compared to some of its other frequencies (3 kHz [$t_{(152)} = -6.432$, $p < 0.001$], and 4 kHz [$t_{(152)} = -5.685$, $p < 0.001$]. There were no significant differences between ears [$F_{(1, 38)} = 0.006$, $p = 0.941$, $\eta^2 = 1.478e^{-5}$] and for test re-test trials [$F_{(1, 38)} = 1.363$, $p = 0.250$, $\eta^2 = 1.343e^{-4}$]. There were no other significant within group factors. Levene's test for equality of variances revealed the data to be consistent and that there are no difference in variances between groups.

3.6 Noise floor comparison between Vivosonic fast and accurate protocol

Figure 9 shows the mean noise floor levels of young adults for the right and left ear between the Accurate and Fast collection settings in Vivosonic's Integrity. The mean noise floor level of the fast protocol was elevated across frequencies compared to the accurate protocol.

Ear: Right



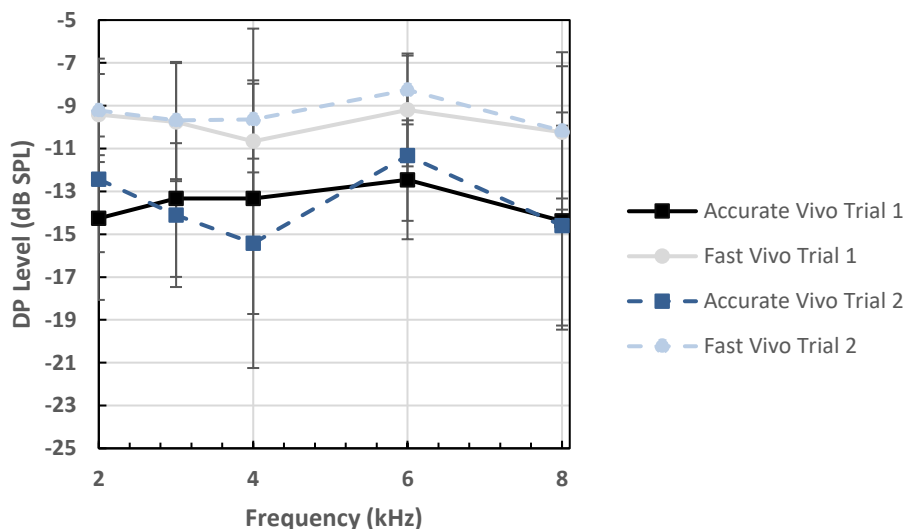
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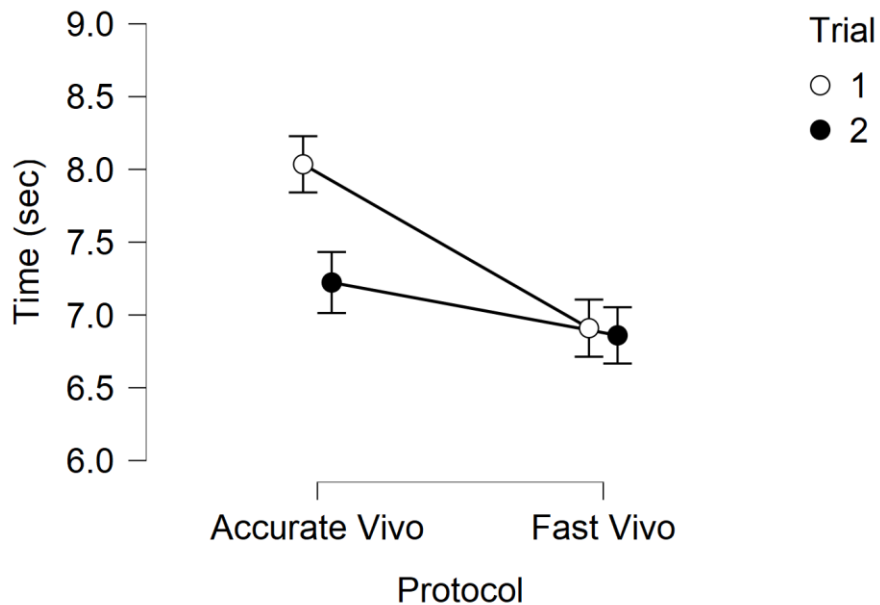
Figure 9. Average noise floor for Vivosonic Integrity's Fast and Accurate data collection protocols for the right and left ear as a function of frequency. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on noise levels with the ear (right and left), trial (1 and 2) and frequency (2000, 3000, 4000, 6000, and 8000 Hz) as within-subject factors and DPOAE measurement protocols of the Integrity (Fast and Accurate) as the between-subject factor. Analysis of the data revealed significant differences between noise floor levels of the two protocols [$F_{(1, 38)} = 30.114, p < 0.001, \eta^2 = 0.193$] implying that the noise floor level between both protocols were different across frequencies. There were also significant noise floor level differences within-subjects regarding frequency [$F_{(2.712, 103.060)} = 7.066, p < 0.001, \eta^2 = 0.035$]. Bonferroni post hoc t-tests were used to examine these interactions. The noise floor levels at 6 kHz were significantly elevated when compared to its 8 kHz noise floor level [$t_{(152)} = 4.494, p < 0.001$] across both protocols. There were no significant differences at other frequencies or between ears [$F_{(1, 38)} = 1.064, p = 0.309, \eta^2 = 0.001$] and between trials [$F_{(1, 38)} = 1.716, p = 0.198, \eta^2 = 8.220e^{-4}$]. There were no other significant within-subject factors. Levene's test for equality of variances revealed that variances differed between the two measures at trial 1 right ear 6 kHz ($p = 0.011$), trial 1 left ear 2 kHz ($p = 0.009$) and 8 kHz ($p = 0.029$), trial 2 right ear 2 kHz ($p < 0.001$) and trial 2 left ear 4 kHz ($p = 0.008$) and 6 kHz ($p = 0.021$).

3.7 Probe check time comparison between Vivosonic fast and accurate protocol

In Figure 10, the mean probe check time of the Fast and Accurate test protocol for DPOAE testing in Vivosonic's Integrity across two different trials were plotted. Figure 10 shows that the mean probe check times of Trial 1 were elevated compared to Trial 2 across protocols in the left ear. In the right ear, this was only shown in the accurate protocol whereas in the fast protocol, times were consistent with one another.

Ear: Right



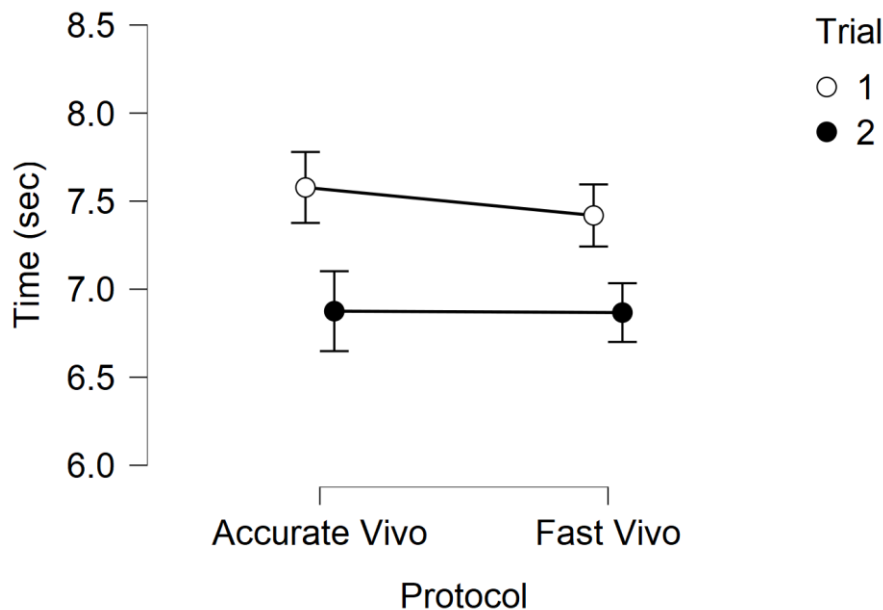
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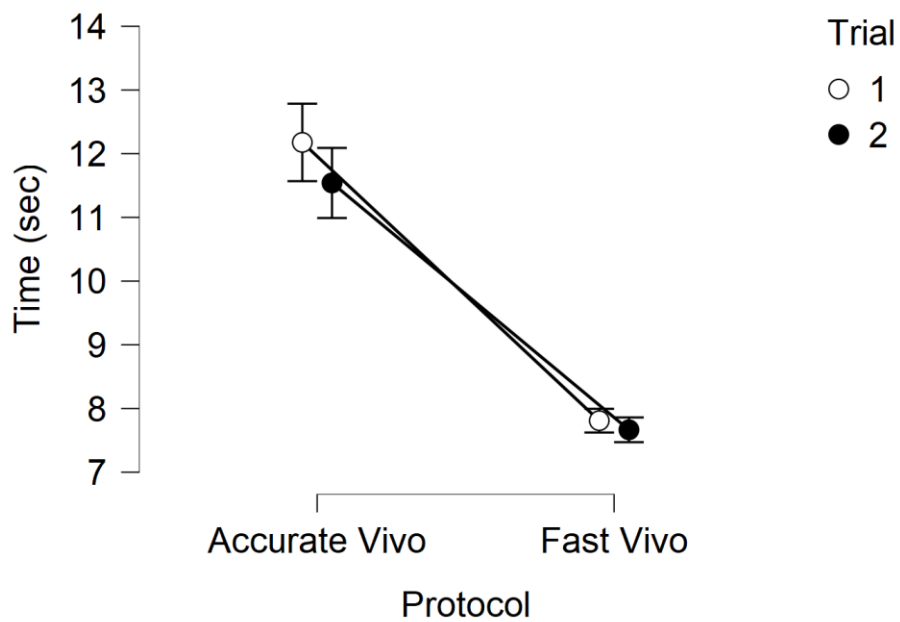
Figure 10. Average probe check time (in seconds) between Fast and Accurate protocols in Vivosonic's Integrity for the right and left ear. Error bars around the mean represent ± 1 standard deviation.

A RMANOVA was carried out on probe check time with the ear (right and left), and trial (1 and 2) as within-subject factors and DPOAE measurement protocols of the Integrity (Fast and Accurate) as the between-subject factor. Analysis of the data revealed no significant differences in probe check time between protocols [$F_{(1, 38)} = 3.365, p = 0.074, \eta^2 = 0.036$]. There were significant differences within-subjects regarding trials [$F_{(1, 38)} = 12.081, p = 0.001, \eta^2 = 0.059$] and a significant interaction between ear and protocol [$F_{(1, 38)} = 5.931, p = 0.020, \eta^2 = 0.023$]. Bonferroni post hoc t-tests showed the average probe check time of trial 1 to be significantly longer than that of trial 2 for both protocols [$t_{(38)} = 3.476, p = 0.001$]. Further, comparisons between the right ear of both protocols was determined to be significantly different and show that the accurate protocol has a longer probe check time compared to the fast protocol in the right ear [$t_{(38)} = 2.827, p = 0.038$]. There were no significant differences between ears [$F_{(1, 38)} = 0.285, p = 0.597, \eta^2 = 0.001$], and other within-subject factors. No 3-way interaction effects between trials, ears and protocols were reported [$F_{(1, 38)} = 3.456, p = 0.071, \eta^2 = 0.005$].

3.8 Test time comparison between Vivosonic fast and accurate protocol

Figure 11 shows the mean test time of young adults for the right and left ear across two different test protocols in Vivosonic's Integrity. As can be seen from Figure 11, the mean test time for Accurate protocol was elevated compared to the Fast protocol.

Ear: Right



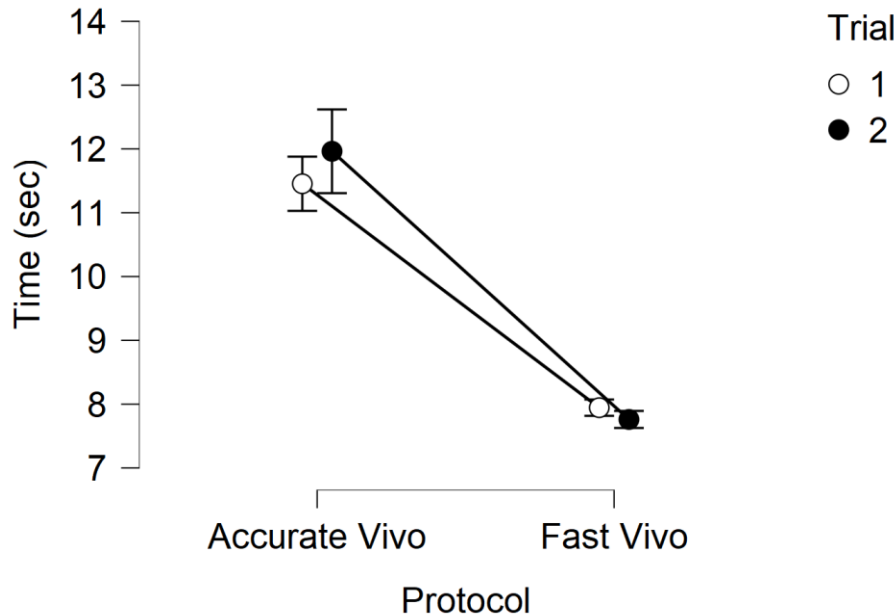
Ear: Left

Figure 11. Average test time between Fast and Accurate protocols for Vivosonic's Integrity DPOAE measurement for the right and left ear. Standard error bars represent ± 1 standard deviation.

A RMANOVA was carried out on test time with the ear (right and left), and trial (1 and 2) as within-subject factors and DPOAE measurement protocols (Fast and Accurate) as the between-subject factor. Analysis of the data revealed significant differences in total test time between protocols [$F_{(1, 38)} = 59.579, p < 0.001, \eta^2 = 0.440$]. Bonferroni post hoc t-tests comparing the accurate and fast test protocols revealed significant differences in test time [$t_{(38)} = 7.719, p < 0.001$], with average accurate test protocol test time being elevated. There were no significant differences between ears [$F_{(1, 38)} = 0.002, p = 0.967, \eta^2 = 8.592e^{-6}$], trials [$F_{(1, 38)} = 0.230, p = 0.635, \eta^2 = 3.587e^{-4}$] and other within group factors.

Chapter 4

4 Discussion

4.1 Summary of Results

In this study, we looked to examine the performance of three clinically used DPOAE measurement systems and to contrast interpretations of DPOAE levels, noise floor level and to examine test time required for completion of a DPOAE test. The DPOAE results from three different OAE measurement systems were studied in young, normal hearing adults for whom there were no significant differences in hearing thresholds. To control for bias effects, test order of the three instruments and starting ear when testing each instrument were counterbalanced and randomized. Group data showed that there were no differences in DPOAE level among the three instruments yet there were significant differences in noise floor level and average test time, suggesting differences in averaging algorithms.

4.2 Comparison between systems

4.2.1 DPOAE Levels

The results from the study show fluctuations in averaged DPOAE levels across instruments which are consistent to DPOAE norms established by Gorga et al. as seen in Figure 5. The average DPOAE levels for all three instruments were consistent with normal hearing by falling above the 95th percentile for impaired hearing. This was expected considering normal hearing participants were recruited. When examining the Scout and Titan DPOAE levels, they were seen to generally decrease as test frequency increased while the Integrity system showed consistent DPOAE levels across test frequencies. Despite these variations, DPOAE levels did not significantly differ between instruments at most test frequencies. These general trends in DPOAE levels as a function of frequency are also showcased in other literature whereby as infants aged, DPOAE levels were also seen to decrease as frequency increased (Abdala et al., 2008, Prieve et al., 1997). This validates that all three instruments can accurately and effectively measure DPOAEs (Gorga et al., 1997; Dorn et al., 1999).

However, averaged DPOAE levels recorded at 8 kHz using the Titan system were significantly lower in comparison to other test frequencies and to the DPOAE level of the Scout and Integrity at 8 kHz. It is reasonable to suggest that the difference in DPOAE level at 8 kHz observed between systems could be attributed to differences in probe tone calibration levels and system processing. Recall that results from the coupler calibration process revealed that the Titan produced a lower stimulus level in comparison to the other instruments at 8 kHz, which could cause the difference in DPOAE levels.

4.2.2 Noise Levels

In this study, noise floor levels were seen to vary based on system and frequency. Firstly, noise floor levels were shown to be elevated at lower frequencies in both Scout and Titan whereas the Integrity's noise floor estimates were relatively flat across all test frequencies. Despite variations across instruments, these results align with previous studies examining the effect of noise on OAE measurements. Gorga et al. (1993) examined DPOAE responses from normal-hearing- and hearing-impaired ears and reported that low frequency OAE recordings have higher noise levels. This is also consistent with findings from Ramos (2013) where the average noise floor decreased from an average of -18.3 dB SPL at 2 kHz to -19.7 dB SPL at 8 kHz. However, comparing the magnitude of noise revealed significant differences between instruments, with Titan having the lowest noise levels, Scout having elevated noise floor levels, and the Integrity having the highest reported noise floor levels.

It is important to understand that noise comes in many forms including external acoustic background noises, and internal noises such as interference from electrical and magnetic signals of the test system and movement from the individual being tested introducing acoustic noise (Gorga et al., 1993; Torre et al., 2003). Fortunately, DPOAE measurement systems obtain clearer results by exploiting differences in signal properties between noise and stimulus and thus reducing noise during response estimation. The effect of noise can be greatly reduced by averaging the DPOAE signal over time. The longer a signal is averaged, the lower the noise level will be (Vaseghi, 2008). In the present study, when each individual instruments' averaged noise floor levels were correlated with their respective DPOAE test time results, it was shown that the Titan has the longest test time, implying greater averaging duration, and corresponding lower noise floor levels. Therefore, it is

possible that the established noise levels within each system differed due to a combination of factors including how each system processes DPOAEs, how different system builds introduce varying levels of internal noise, and varying fits of the probes to individual ears (Popelka et al, 1998, Zhang & McPherson, 2008).

4.2.3 Test Times

Since the ability to conduct a DPOAE test rapidly is an important consideration for newborn hearing screening, it is germane to examine the testing time in all three instruments. Testing time in a DPOAE test was broken down into two components, an probe fit check phase and a DPOAE testing phase.

Before a DPOAE test can be initiated, an initial probe fit check is performed to ensure there is no leakage in sound and that there is no occlusion of the presented signal by measuring the SPL of the probe tone signals (Vivosonic, 2021). The initial probe fit check typically uses a composite signal that encompasses the entire frequency test spectrum and is presented once an appropriate probe tip is placed in an individual's ear. Once an adequate seal is achieved with the probe tip and a DPOAE test is initiated, probe-tip calibration processes occur within each instrument. While maintaining a specific frequency and level ratio, a measure of the SPL is analyzed by simultaneously applying two signals to be captured by two receivers within the OAE probe whereby the actual sound pressure levels of the two tones are analyzed and compared to what is generated in a participant's ear canal to ensure a seal is maintained during testing. The study shows that the Integrity and Scout both take greater than 6 seconds on average to conduct a probe fit check with the Scout taking the longest of the three instruments. However, Titan showed significantly shorter probe check time in comparison to other instruments. These differences can be attributed to how a probe fit check is performed in the varying systems.

Initialization of the probe fit check is dependent on the user starting the DPOAE test for the Scout and Integrity system. On the other hand, an initial probe fit check within the Titan system is initiated without requiring a user to start the DPOAE test. Therefore, once a DPOAE test was initiated, the probe fit check was already passed, thus resulting in a low probe fit check time.

In comparison, the test time of the machines was shown to be inverse to the probe check time. As aforementioned, the Titan is shown on average to take the longest when conducting a DPOAE test while the Scout took the shortest amount of time among the three instruments. All three instruments utilized the same testing protocol whereby all devices were allowed up to 15 seconds per test frequency to meet the desired SNR criterion of greater than 8 dB. However, as different instruments achieved this pass criteria after different durations, these differences can be attributed to variations in signal averaging schemes which are specific to each device (Dhar & Hall, 2018).

4.3 Comparison between protocols within the Integrity system

To the best of our knowledge, no study has been conducted on analyzing the differences between Vivosonic Integrity's "fast" and "accurate" collection protocols. According to the Integrity user's manual, these protocols are used to define the speed and accuracy of the DPOAE measurement. Fast setting accepts a DPOAE measurement if the DPOAE signal is stable within ± 3 dB for 0.2 seconds. Accurate setting on the other hand requires that the DPOAE signal be stable within ± 1 dB for a longer period (0.4 seconds). As shown in Figure 11, the accurate protocol increased measurement time per frequency during a DPOAE test which allows the Integrity system more time to average the signal using their unique averaging techniques, thus reducing the noise in comparison to the fast protocol settings as seen in Figure 9. This difference in test time was also shown in Figure 9 where the accurate protocol took significantly longer in comparison to the fast protocol. These results provide evidence that the accurate protocol has utility when concerns of noise are high whereas the fast protocol is ideal when looking to screen individuals or infants for faster results.

When examining DPOAE levels between protocols, they shared consistent response levels across frequencies, with an increased level at 6 kHz. Since the same instrument was utilized with the only difference being the setting for accuracy, it was expected that both protocols would yield similar results. Similarly, when examining our calibration results, it is shown that there are no significant elevated stimulus levels, including at 6 kHz, compared to other test frequencies within the Integrity system. As such, the elevation in DPOAE levels at 6

kHz could be attributed to the system's unique averaging algorithms or to the systems probe-tip calibration process.

Lastly, the probe check times between protocols were shown to be similar. However, there are similar differences in these times between trial 1 and trial 2 of recordings for both protocols. As shown in Figure 8, the first trial on average took longer than the second trial. This may be attributed to how the software operates. It can be speculated that the time difference between trial 1 and trial 2 is due to the system is initializing the DPOAE test for the first time in trial 1 which requires some time. When starting trial 2, the system has already been primed and initialized from trial 1, thus resulting in a faster test. Despite trial 2 being faster, when put into the perspective of the total amount of time required to conduct a DPOAE test, the variability in probe check time is negligible and should not influence a clinician's decision when deciding what protocol to utilize.

4.4 Clinical Implications

This study has shown the effectiveness of conducting DPOAE testing among three measurement systems and more importantly, that all systems can provide evidence of normal hearing as DPOAE levels are shown to fall above those typical for ears with hearing impairment. Despite there being variations among the test times of the different systems, it is important to consider the magnitude of these differences. These differences are on the order of seconds and are therefore generally not clinically important. This implies that speed of testing offers no basis for choosing one instrument over another. Furthermore, this study looked to verify differences between accuracy settings within the Integrity system. The study has clinical relevance by verifying that accurate settings provide better estimates by reducing noise levels through longer measurement time, whereas fast settings provide estimates in a shorter amount of time. This can be useful as verification of these settings will allow researchers and clinicians to adapt to different OAE testing situations. For example, if used for newborn hearing screening, we now have evidence that the fast setting will provide faster estimates which can be important when working with newborns. On the other hand, if looking at the effects of ototoxic drugs on hearing in adults, a higher level of accuracy would prove beneficial. Furthermore, despite the accurate mode not being explicitly available on other systems, it can be inferred that if the appropriate parameters

are chosen across all devices, that we could emulate the accurate protocol and that similar DPOAE levels could be found on other measurement systems. Despite these variations in test time which are on the order of a few seconds, all three instruments have demonstrated the capacity to reliably conduct DPOAE testing. Therefore, it should be up to the clinician's preference when choosing a DPOAE measurement system.

4.5 Limitations

There are several limitations that must be considered and rectified in future studies. Despite the inherent nature of OAEs being susceptible to fluctuations due to a variety of factors, it is unknown as to how much this variation is due to the nature of testing as opposed to differing signal processing algorithms in the varying instruments. As each manufacturer's instruments utilize different averaging processes which are unknown to the public, it becomes unclear as to what may be specifically causing differences in DPOAE level, noise floor level, and test times between instruments. However, some of these differences can be explained. Firstly, it is important to note that in this study, participants were asked to wear face masks while DPOAE tests were conducted in compliance with Covid-19 IPAC policies. It is possible that these masks could cause participants to breathe more heavily due to feelings of discomfort. Typically speaking, sources of internal noise such as normal breathing or blood flow in the ear attribute minimal noise (Rasetshwame et al., 2015). However, heavy breathing could increase the levels of low frequency noise which would cause greater variability in noise floor levels. Second, there may have been variations in the probe fit of participants. Measured OAEs will vary depending on the insertion depth of the probe and its coupling to the ear canal, an individual's ear canal acoustics and frequency. Considering that refitting of the probe was conducted after every trial, there will be differences in these parameters which could affect measured OAEs. Furthermore, there is the possibility of an improper fit of the probe tip that may cause reduced stimulus intensity. It is important to note that both probe fit check time and DPOAE test time were quantified using a stopwatch which may introduce variability through operator performance. Therefore, future studies should look to improve processes for collection of test time by using higher precision measures such as automated stopwatches. Furthermore, future studies should look to investigate the difference in averaging algorithms between

manufactures to determine the root cause of variations in noise, test time and DPOAE level calculations. Lastly, future research should be conducted on the DPOAE at frequencies higher than 8 kHz. As our calibration results showed different stimulus levels at higher frequencies, this may affect interpretation of DPOAE results.

4.6 Reference

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Chapter 5

5 Conclusion and Future Direction

The purpose of this study was to examine the performance of three DPOAE measurement systems (Interacoustic Titan, Bio-logic Scout and Vivosonic Integrity) using a modified IHP test protocol on normal hearing adults. The results of these test show minimal differences in recorded DPOAE levels across instruments, yet differences in noise floor levels and testing times. This may suggest that despite normal DPOAE recordings being obtained, differences in signal processing algorithms may exist to cause differences in estimations of noise and overall testing time. However, despite reported differences in test times, the differences are on the magnitude of seconds which may not prove to be significant in real world applications of OAE testing. Therefore, all three devices may prove effective at determine cochlear function.

Lastly, the study also sought to examine differences between OAE accuracy measurement settings using the Integrity system. These settings dictate the speed and depth of detail of an OAE measure. As expected, the test time and noise floor estimates of the more accurate setting were longer and lower respectively while the fast setting on the Integrity conducted DPOAE measures with greater speed but with higher noise estimates. And since both protocols yielded similar DPOAE levels across test frequencies, this suggest that these protocols can be used interchangeably which allows for highly accurate DPOAE testing in various testing situations.

As this study was performed inside a sound attenuated chamber with normal hearing adults only, there is a need to conduct further investigation. We may suggest performing the study on expanding the data pool to incorporate other clinical population (ie. children and hearing impaired) or to conduct the DPOAE testing outside of the sound booth to better understand the differences in signal processing algorithms between instruments. We may also look to examine testing higher frequencies above 8 kHz as OAEs tend to be more affected at higher frequencies which could provide insight into the different signal processing strategies of each instrument. We could also replicate the study by applying different accuracy settings in other devices to verify if findings would be similar across devices. In summary, all three

DPOAE measurement systems and accuracy settings yielded reliable DPOAE measures thus supporting their usage in hearing screening protocols.

Appendices

Appendix A: Approval for Research Involving Human Participants



Date: 10 June 2020

To: Dr. Susan Scollie

Project ID: 113316

Study Title: Auditory Signal Feature Encoding in Adults

Application Type: Continuing Ethics Review (CER) Form

Review Type: Delegated

REB Meeting Date: 16/Jun/2020

Date Approval Issued: 10/Jun/2020

REB Approval Expiry Date: 14/Jun/2021

Dear Dr. Susan Scollie,

The Western University Research Ethics Board has reviewed the application. This study, including all currently approved documents, has been re- approved until the expiry date noted above.

REB members involved in the research project do not participate in the review, discussion or decision.

Western University REB operates in compliance with, and is constituted in accordance with, the requirements of the TriC council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good

Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The REB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Daniel Wyzynski, Research Ethics Coordinator, on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations). Page 1 of 1

Appendix B: Letter of Information and Consent Form

Consent Form

Project Title: Acoustic Signal Encoding in Adults

Principal Investigator: Susan Scollie, Ph.D*
*National Centre for Audiology

I have read the information in this Letter of Information and Consent form. I have had an opportunity to discuss the purpose, methods, risks, potential benefits, and available alternatives of this research. I have been able to ask questions regarding my participation in this research. I have had my questions answered to my satisfaction.

I understand that I may have a copy of this signed and dated consent form.

My participation in this research is voluntary. I agree to participate in this research study.

No legal rights are waived as a result of signing this consent form.

Name (participant)

Name (person obtaining consent)

Signature

Signature

Date:

Date:



Letter of Information

Project Title: Acoustic Signal Feature Encoding in Adults

Principal Investigator: Susan Scollie Ph.D.
National Centre for Audiology, 08/03/2021
University of Western Ontario

Location: National Centre for Audiology
Elborn College, University of
Western Ontario

Sponsor Information: Devices used in this study are provided by manufacturers of hearing testing equipment. These manufacturers are Clearwater Medical (Ottawa, Ontario), and Vivosonic (Toronto, Ontario). They are also providing funds that support personnel and supplies needed to conduct this research. Their future interest in developing and arranging for the sale of these devices is dependent, in some part, on the results of this study. The sponsors will receive de-identified data only.

This study is also funded by the Ministry of Research and Innovation through an Ontario Research Fund- Research Excellence award to the National Centre for Audiology.

Dear Study Participants

Researchers at the National Centre for Audiology invite you to participate in a study that evaluates the efficacy of advanced hearing tests. The purpose of this letter is to tell you about the study so you can decide if you would like to participate. We want you to understand the research project, and its risks and potential benefits. We would like you to make an informed decision about participating in this investigation. This consent form may contain words that you do not understand. Please ask the study investigators to explain any words or information that you do not clearly understand. You may take home a copy of this consent form home to think about before making your decision. You will be given a copy of this consent document once it has been signed.

Description and Purpose of the Research Project: The purpose of this study is to understand how basic features of sound (frequency, intensity, and duration) are coded in the brain. This study will include up to one hundred and twenty (150) people. Results from this study may contribute to more effective methods for hearing assessment.

If you agree to participate, you will be asked to complete a survey to assist us in a better understanding of your hearing history. You will be asked to sit comfortably in a sound booth listening to different sounds while wearing earphones. You will be asked repeat words or report sounds that you have heard. You will also be asked to complete a listening task on a computer or tablet screen (psychoacoustic testing). Your hearing may also be assessed by placing electrodes on your head while a computer automatically records your brain's responses to sound. During the testing, you can relax, and you do not have to do anything (physiologic testing).

Time Commitment: If you agree to participate, we will invite you to see us up to three (3) times. Each visit can take up to 2 hours. We will arrange the visits at your convenience. At each 2-hour visit, you can have rest breaks when needed. The research will take place at the National Centre for Audiology in Elborn College at The University of Western Ontario.

Visits:

Visit	Tests and Procedures
Visit 1 Approximately 2 hours	<ul style="list-style-type: none"> • Intake • Basic Audiological Evaluation • Psychoacoustic testing
Visit 2 Approximately 2 hours	<ul style="list-style-type: none"> • Physiological testing
Visit 3 Approximately 2 hours	<ul style="list-style-type: none"> • Physiological testing may continue

Risks: This study will involve no known risk to you. The use of surface electrodes requires that we clean the skin with a small cleaning pad and a gel. During the cleaning process, we gently rub the skin where the electrode will be placed, but this does not usually cause discomfort.

Benefit to you: Although there may not be any direct benefit to you, some benefit may include having an up to date hearing assessment.

Benefit of this study for society: The outcome of this project may enhance the understanding of auditory processing in normal hearing- and hearing-impaired adults. The result of this research is expected to improve the knowledge of psychoacoustic and electrophysiological measures. Which in turn may help in changing/improving the standard clinical practice.

Confidentiality: Your name and email address will be collected so that study staff can contact you during the study. This information is kept separate from study data. We will be collecting your name and signature on the form attached to this letter. This form will be kept separate from any data collected.

Paper records will be stored in a locked cabinet in a secure office. We protect your confidentiality by assigning you an identification number. All data will be de-identified and correspond only to the identification number. Electronic data obtained in this study will be stored in a network drive. This network drive can be only be accessed by authorized personnel. The National Centre for Audiology will use the information from this study for scientific purposes. Data collected may be included in scientific reports. Your name will not appear in any publication. Any data shared with the manufacturers will include the identification number only.

We retain the de-identified collected research data indefinitely. All identifiers will be destroyed according to the institutional policy after 7 years in accordance with the University of Western Ontario's recommended practice for destroying data.

While we will do our best to protect your information there is no guarantee that we will be able to do so. There is always the risk of a privacy breach. Please also note that email communication is not a secure method of communication.

Representatives of the University of Western Ontario Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of the research.

Compensation for Injury:

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

Compensation: We will compensate you \$10 per hour during the study visits. We will also provide a parking pass when you arrive for your sessions.

Sponsor Information: The Ministry of Research and Innovation is providing funds for this study through an Ontario Research Fund Grant. Some devices used in this study are provided by Ontario industry partners on this grant. They include Clearwater Medical (Ottawa, Ontario), Audioscan (Dorchester, Ontario), Unitron Hearing (Kitchener, Ontario), and Vivosonic (Toronto, Ontario). As partners, they would receive de-identified data only. The grant partners intend to claim ownership of the research results consistent with this consent. By signing this consent, you agree that the manufacturers can apply for patents and you will not receive any financial benefit that might come from the research.

Voluntary Participant and Withdrawal: Participation in this study is voluntary. You can refuse to participate. You can refuse to answer any questions. You can withdraw from the study at any time. You can choose to participate in other research studies at the National Centre for Audiology even if you choose not to be in this study. If you withdraw from the study, your de-identified information will not be sent to the industry partners, as your data will be destroyed according to the University of Western Ontario's procedures.

Legal Rights: No legal rights are waived by the signing of the consent form.

Questions: If you wish to obtain additional information regarding this project, please contact the principal investigator Susan Scollie

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Human Research Ethics (519) 661-3036, 1-844-720-9816, email: ethics@uwo.ca. The REB is a group of people who oversee the ethical conduct of research studies. The HSREB is not part of the study team. Everything that you discuss will be kept confidential. Representatives of the University of Western Ontario Health Sciences Research Ethics board may contact you or require access to your study-related records to monitor the conduct of the research.

This letter is for you to keep.

Sincerely,

Susan Scollie, PhD
Principal Investigator

Prudence Allen, PhD
Co-investigator

Sarganatha A V, PhD
Project coordinator

14/06/2019

4

Curriculum Vitae

Name: Maximilian Tran-Luong

Post-secondary University of Toronto

Education and Toronto, Ontario, Canada

Degrees: 2014 - 2017 B.Sc

The University of Western Ontario

London, Ontario, Canada

2018 - 2021 M.Sc

Honours and Western Graduate Research Scholarship (WGRS)

Awards: 2018 – 2020

Related Work Graduate Teaching Assistant

Experience: The University of Western Ontario

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