ABSTRACT

Title of Document: THE EFFECT OF BODY POSITION ON DISTORTION PRODUCT OTOACOUSTIC EMISSIONS TESTING IN NEONATES

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The current study investigated the effects of body position on the measurement of distortion product otoacoustic emissions (DPOAEs) in newborns. DPOAE measurements are commonly used to screen for hearing loss in newborn hearing screening programs conducted in hospitals nationwide. To measure DPOAEs, a small probe is placed in the external ear canal and a series of tone pairs is presented to the ear. The ear's acoustic response to these tones is measured to determine if the infant is at risk for a hearing loss. Research in adults has indicated effects of body position on DPOAE levels and noise floor levels (Driscoll et al., 2004). However, no information is available on the effects of body position on DPOAE testing in infants, despite the fact that newborn screening is one of the primary clinical applications of DPOAEs. Participants were 47 full-term newborns recruited from the well-baby nursery. DPOAEs were measured from the right ear while the infants were in each of three body positions: lying on the left side, supine, and head raised 45 degrees from supine. DPOAE levels, noise floor levels,

DPOAE/noise levels, test time, and pass/fail rate were compared across body positions to determine whether there is an optimal body position for newborn hearing screenings that would minimize test time and/or increase specificity. No statistically significant differences were found in the various DPOAE measures or screening results across body positions or between genders. Significant effects of frequency on DPOAE levels and noise floor levels were similar to those expected based on the literature (e.g., Gorga et al., 1993). The results suggest that newborn hearing screenings on infants in the well-baby nursery can be conducted in different body positions without significantly influencing the screening outcome or measurements obtained.

THE EFFECT OF BODY POSITION ON DISTORTION PRODUCT OTOACOUSTIC EMISSIONS TESTING IN NEONATES

By

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Dedication

This dissertation is dedicated to my family and friends. Thank you to Mom, Dad, Nick, Lauren, Grandma, Grandpa, and Jodi for all of your support throughout this process and for always believing in me. Thank you to Justine, Kara, Nicole and Matt for your friendship.

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Chapter 1: Introduction

Moderate to profound hearing loss occurs in healthy neonates with no risk factors for hearing loss about one to six times out of 1000 (e.g., Watkin, Baldwin, and McEnerny, 1991). The age at which congenital hearing loss is identified has a significant impact on later language development. Children who are identified before six months of age have higher scores on later tests of receptive and expressive language when compared to children identified after six months of age. The differences in language development as a function of age of identification hold true regardless of a child's age, degree of hearing loss, gender, mode of communication, minority status, socioeconomic status, and other disabilities (Yoshinaga-Itano, Sedey, Coulter, & Mehl, 1998). This strongly supports the need for effective universal newborn hearing screening programs to facilitate identification of and intervention for congenital hearing loss as early in life as possible.

Because infants cannot say when they hear a sound, newborn hearing screening programs are based on the use of objective physiologic test methods (Norton et al., 2000a). This type of test measures a physiologic response to a stimulus without the need for a behavioral response. Otoacoustic emissions (OAEs) testing is one noninvasive physiologic method of screening for hearing loss in newborns (Gorga et al., 2000; Gorga, Preissler, Simmons, Walker, & Hoover, 2001; Norton et al., 2000b).

OAEs are soft sounds produced by the healthy cochlea (inner ear) and are measured using a small microphone placed in the ear canal. OAEs may occur spontaneously or may be evoked in response to a stimulus (Kemp, 1978). The type of

evoked OAE of interest for this study is distortion product otoacoustic emissions (DPOAEs). DPOAEs are tones measured in the ear canal during stimulation with two pure tones (Gorga et al., 1993; Lasky, Perlman, & Hecox, 1992; Lonsbury-Martin & Martin, 1990). The nonlinear behavior of the outer hair cells in the cochlea results in emitted energy at frequencies that are different from the two pure tone stimuli (Gaskill & Brown, 1990; Gorga et al., 1993; Kemp, 1979).

Evoked OAEs (EOAEs), such as DPOAEs, are used to measure cochlear outer hair cell function and have been shown to be highly correlated with peripheral hearing sensitivity (Fitzgerald & Prieve, 2005; Gaskill & Brown, 1990; Gorga et al., 1993; Gorga et al., 1997; Hussain, Gorga, Neely, Keefe, & Peters, 1998; Norton et al., 2000b). EOAEs can be reliably recorded in response to stimulus frequencies above 1500 Hz in neonates with hearing sensitivity better than 30-50 dB HL (Norton et al., 2000a). Measurable EOAEs are considered an indicator that cochlear function is normal and, therefore, that hearing is likely normal. Absent EOAEs are considered an indicator that an ear is at risk for hearing loss.

Utilizing EOAE testing in newborn hearing screening programs results in a low false positive rate (less than 4 percent); therefore, EOAEs are a relatively cost effective and efficient method of screening for congenital hearing loss (Gorga et al., 2001; Norton et al., 2000b). However, improved efficiency is always beneficial, because the cost of false positives is great. In newborn hearing screening programs, false positive results lead to unnecessary testing and to stress and anxiety for new parents (Weichbold, Phil, & Welzl-Mueller, 2001). False positives increase the cost and time required for follow-up in a universal newborn hearing screening program.

Therefore, it is necessary to determine the most efficient method of screening for hearing loss in newborns.

Several studies have indicated that body position can affect OAE and noise floor levels during testing in adults, likely due to differences in intracranial pressure in different body positions (e.g., Antonelli & Grandori, 1986; de Kleine, Wit, Avan, & van Dijk., 2001; Driscoll, Kei, Shyu, & Fukai, 2004; Phillips & Farrell, 1992; Voss, Folowosele, Shera, Horton, and Tabucchi, 2006). This raises the possibility that body position may have an effect on infant OAE testing, as well. If there are significant differences in OAE measurements observed in different body positions in newborns, body position would have to be accounted for during newborn DPOAE screening procedures.

The goal of this study was to compare the effects of body position on DPOAE screening results from neonates in a hospital nursery. Infants were screened using DPOAEs while lying in three positions commonly used during hearing screenings: on the left side ("one-sided"), supine, and with the head raised 45 degrees from supine ("head-raised"). DPOAE levels, noise floor levels, DPOAE/noise, test time, and pass/fail rate were compared across body positions. Results also were examined for gender and frequency effects.

Chapter 2: Review of Literature

Otoacoustic Emissions

Otoacoustic emissions from the human auditory system were first described by Kemp in 1978. In the original study, Kemp measured echoes in the external auditory meatus with a probe microphone and described the measured echoes as being dependent on the frequency of the stimulus input. Responses were measured in a small number of participants with normal hearing, participants with cochlear hearing loss, and participants with a conductive hearing loss. Emissions were measurable in those with normal hearing and absent in those with hearing losses greater than 30 dB HL of both conductive and sensorineural origin (Kemp, 1978). Since Kemp first made this observation it has been confirmed that the presence of measurable otoacoustic emissions is influenced by both middle ear and cochlear status (e.g., Gaskill & Brown, 1990; Gorga et al., 1993; Gorga et al., 1997; Hussain et al., 1998; Lonsbury-Martin, Martin, McCoy, & Whitehead, 1994; Owens, McCoy, Lonsbury-Martin, & Martin, 1993).

Based on the absence of the measured emissions in a non-living human ear model, Kemp (1978) concluded that they are a phenomenon particular to the living auditory system. The non-linear nature of the emissions led Kemp to hypothesize that a cochlear reflection was occurring in response to the stimuli. He further hypothesized that the cochlear outer hair cells were responsible for the measured emissions (Kemp, 1978, 1979). The early hypotheses by Kemp regarding the origins and characteristics of the measured emissions have since been confirmed and expanded upon by other researchers (e.g., Brownell, Bader, Bertrand, & de

Ribaupierve, 1985; Gaskill & Brown, 1990; Kim, 1980). It is hypothesized that OAEs are a byproduct of the cochlear amplifier, the mechanism responsible for increasing the vibration of the basilar membrane at the characteristic place for the frequency of a stimulus (Davis, 1983). The cochlear amplifier is believed to contribute to enhanced hearing sensitivity, frequency selectivity, and the large dynamic range of a healthy cochlea (Davis, 1983).

Research has indicated that damage to the outer hair cells results in decreased hearing sensitivity, broader frequency selectivity, and a reduced dynamic range. Therefore, outer hair cells are believed to be the source of the cochlear amplifier mechanism and the generators behind OAEs (Khanna & Leonard, 1986a; Khanna & Leonard, 1986b). The hypothesis that the outer hair cells are responsible for measurable OAEs is supported by the absence of measurable OAEs following damage to the outer hair cells from exposure to noise or ototoxic medications (Brown, McDowell, & Forge, 1989; Hamernik, Ahroon, & Lei, 1996).

Traditionally, OAEs have been divided into two main types: spontaneous and evoked. Spontaneous otoacoustic emissions (SOAEs) are low-level, tonal signals that are measured in the ear canal in the absence of a stimulus (Kemp, 1979). These emissions are nearly always inaudible and are found in frequency regions where hearing sensitivity is normal (Probst, Lonsbury-Martin, Martin, & Coats, 1987). In individuals with measurable SOAEs, robust evoked otoacoustic emissions are evident in the frequency region where SOAEs are present (Prieve, Fitzgerald, Schulte, & Kemp, 1997; Probst, Coats, Martin, & Lonsbury-Martin, 1986). SOAEs are typically measurable in the limited frequency range of 1000-2000 Hz in adults; however, in

neonates SOAEs may be measurable at frequencies up to 5000 Hz (Burns, Arehart, & Campbell, 1992). SOAEs are not used for clinical applications, because not all ears with normal hearing produce them. SOAEs are expected to be measurable in approximately 50-70 percent of ears with normal hearing in the general population (Penner & Zhang, 1997; Strickland, Burns & Tubis, 1985). It is as yet unclear whether the prevalence of SOAEs in newborns is higher than the prevalence in adults. One study estimated that SOAEs are present in up to 78 percent of healthy newborn ears (Kok, van Zanten, & Brocaar, 1993), while other studies have failed to find a significant difference between the prevalence of SOAEs in newborns compared to adults (Strickland et al., 1985).

Evoked OAEs are measured in response to the presentation of a sound stimulus to the ear. Since Kemp's first report on OAEs, two means of measuring/evoking the emissions have become commonly-used clinical tools. Transient evoked otoacoustic emissions (TEOAEs) are measured following the presentation of brief stimuli such as clicks or tone bursts (Hussain et al., 1998). TEOAEs measured in response to click stimuli are sometimes used for newborn hearing screenings (Norton et al., 2000c). Distortion product otoacoustic emissions (DPOAEs) are the second type of EOAEs used clinically and are the focus of the present investigation.

Distortion Product Otoacoustic Emissions

DPOAEs were first discovered by Kemp in 1979. They are a product of the nonlinear behavior of the healthy cochlea (Gaskill & Brown, 1990; Gorga et al., 1993 Kemp, 1979). This nonlinear behavior results in an output of energy that is different

from the stimulus input. DPOAEs are measured in the external auditory canal during the simultaneous presentation of two pure tones, "f1" and "f2", to the ear (Gorga et al., 1993; Lasky et al., 1992; Lonsbury-Martin & Martin, 1990). These two pure tones are also known as the "primaries" (Gaskill & Brown, 1990). In response to the primaries, the ear will produce tones at other frequencies. The strongest emission is typically measured at the frequency of 2f1-f2, known as the cubic distortion product (Gaskill & Brown, 1990). The tone at 2f1-f2 is the DPOAE that is measured for clinical testing. Narrowband filtering is used to isolate the response in the frequency region of the cubic distortion product.

The level of the 2f1-f2 DPOAE measured in the ear canal is dependent on many factors, including the frequency separation of the two stimulus tones (f2/f1). An f2/f1 ratio of approximately 1.2 results in the largest emission on average across normal-hearing ears (Abdala, 1996; Gaskill & Brown, 1990). Therefore, the two areas along the cochlea that f1 and f2 are stimulating are close together in place. The intensity level difference that produces the largest 2f1-f2 emission changes as a factor of the overall stimulus level. At lower stimulus levels, the level of f1 should be higher than that of f2 in order to record the largest 2f1-f2 levels. As the overall level increases, the optimal level separation between f1 and f2 decreases. Thus, a difference of 10 to 15 dB between f1 and f2 for low-level stimuli (i.e., 40 dB SPL) and a difference of 0 dB for higher-level stimuli (i.e., 75 dB SPL) results in the largest emissions (Gaskill & Brown, 1990).

DPOAE levels change throughout the lifespan (Dorn, Piskorski, Gorga, Neely & Keefe, 1998; Lasky et al., 1992; Prieve et al., 1997). Although changes with

advanced age are more controversial, it is generally accepted that infants have significantly higher DPOAE levels than adults or older children (Prieve et al., 1997). It also has been shown that noise floor measurements made during OAE testing are significantly higher in infants than in adults (Bergman, et al. 1995; Lasky et al., 1992; Smurzynski et al., 1993). This has been found over the entire frequency range, with noise levels approximately 5 dB higher in infants compared to levels measured in adults.

Findings with regard to gender effects and DPOAEs have been conflicting. Most of the studies reporting on the differences in DPOAEs between males and females have found that females exhibit larger DPOAEs than males, but this difference does not appear to be clinically significant (Cacace, McClelland, Weiner, & McFarland, 1996; Gaskill & Brown, 1990). Morleta et al. (1996) demonstrated small differences in OAEs between males and females in neonates, indicating larger measurable OAEs in females, but this finding failed to reach statistical significance. Research has not shown any significant difference in the recordings of DPOAEs in right ears versus those in left ears (Lonsbury-Martin et al., 1997).

Previous work has indicated that DPOAE levels remain fairly stable within a given ear over multiple measurements, both within a test session and when measurements are made on different days, particularly for f2 frequencies above 1000 Hz. Changes in the probe fit (position of the probe in the ear) appear to have the greatest impact on test-retest differences (e.g., Zhao & Stephens, 1999). In one study, short term variance of DPOAEs within one test session was small, with a variance of less than 3 dB in 12 normal-hearing participants with a mean age of 32.3 years (Zhao

& Stephens, 1999). This study used an f2/f1 ratio of 1.22 and equal-level primaries presented at 70 dB SPL for the f2 frequencies of 637 Hz to 5582 Hz. Changing the probe fit had a significant effect on the level of background noise recorded by the probe and was believed to be the source of the majority of variance in DPOAE level observed (Zhao & Stephens, 1999). The differences in noise levels were seen primarily for the recordings using stimuli below 1000 Hz. Longer-term stability of the recordings (over a four-week period) revealed variations of reproducibility similar to those observed from refitting the probe on the same day. There were no significant differences that could not be accounted for by probe fit (Zhao & Stephens, 1999). These findings demonstrate that the actual emission is stable over time and extrinsic influences (e.g., probe fit) can account for differences in the emissions recorded during various test sessions and conditions (Zhao & Stephens, 1999). The authors of this study claimed OAE stability over a long period of time; however, the study was actually only reporting on the stability over the span of a four-week time period in young normal hearing listeners.

Beattie, Kenworthy, and Luna (2003) reported test-retest reliability of DPOAEs in a group of 50 women between the ages of 19-27 years. Testing was repeated in three time intervals: (1) within one test session without refitting the probe, (2) in the same test session with a short break and probe removal and reinsertion, and (3) after a five to ten day interval following the initial test session. The findings indicated test-retest reliability within 5 dB of the measured response for 1000 Hz to 4000 Hz and within 10 dB of the measured response at 550 Hz for the three time intervals evaluated. The authors of this study attribute the frequency effect to low

frequency noise present in the ear canal from probe fit and the effect of middle ear pressure/characteristics on lower frequencies (i.e., 550 Hz) (Beattie et al., 2003). The stability of DPOAE levels over time has been supported by other studies with a range of reported standard deviations between two tests of approximately .75 dB to 3 dB (e. g., Cacace et al., 1996; Fitzgerald & Prieve, 2005; Franklin, McCoy, Martin, Lonsbury-Martin, 1992; Roede, Harris, Probst, & Xu, 1993).

A recent study reported on the differences between the variability obtained with a single probe fit compared to multiple probe insertions for the frequency range of 1000 Hz to 6000 Hz (Wagner et al., 2008). The DPOAE measurements for this study were conducted in a quiet clinic room in 44 normal-hearing adult participants (Wagner et al., 2008). The authors reported the "Sm", which is the "[standard deviation] of a subject's all measured values multiplied by the square root of 1 minus the reliability" (Wagner et al., 2008, p. 382) and is analogous to the standard deviation. When successive measurements were made without refitting the probe, the Sm was .67 dB (Wagner et al., 2008). When successive measurements were made with multiple probe fits, a Sm of 1.4 dB was reported (Wagner et al., 2008).

Lasky, Perlman, & Hecox (1992) compared DPOAEs obtained in ten neonates and ten adults and reported on between-subject variability and intra-subject variability within one test session. Lasky et al. (1992) did not provide values for a direct comparison between adults and neonates but noted greater test-retest variability in their sample of neonates compared to their sample of adult participants. They further noted that differences in test-retest variability were primarily related to noise floor

level variability and variability was less obvious in DPOAE level measurements (Lasky et al., 1992).

Hearing Screening with DPOAEs

Universal newborn hearing screening programs aim to accurately and efficiently identify significant, permanent congenital hearing loss as early in life as possible. Ideally, a hearing screening measure would differentiate between those with hearing loss and those with normal hearing sensitivity 100 percent of the time. If an incidence of one infant with significant, permanent hearing impairment per 1000 is assumed (Watkin et al., 1991), a fail rate of approximately .001 percent would be predicted. Unfortunately, auditory clinicians and scientists have yet to identify a perfect screening measure; therefore, some false negative and false positive results are expected (e.g., Gorga et al., 1997; Johnson et al., 2005). In addition, time and cost are vital factors in the feasibility of a screening program and must be balanced against accuracy. False positive results greatly add to the cost of a screening program. Besides causing stress and anxiety for new parents (Weichbold et al., 2001), false positives results lead to unnecessary time and resources spent on follow-up procedures. DPOAEs are considered to provide reasonably accurate screening results, while also providing cost-effective and efficient results. In a large study evaluating the use of DPOAEs as a screening tool for infants, DPOAEs resulted in a false positive referral rate of less than 4 percent with an overall referral rate of approximately 12 percent (Gorga et al., 2000; Norton et al., 2000b).

The sensitivity of DPOAEs as a screening tool increases with greater hearing loss (Gorga et al., 1997; Norton et al., 2000b). Therefore, DPOAEs are a tool that

more accurately identifies moderate or greater hearing losses and false negative results are most likely to involve mild hearing losses (Gorga et al., 1997). The sensitivity of DPOAEs also varies as a function of frequency. DPOAEs have been shown to be more accurate at describing mid-frequency to high-frequency (f2 = 2000-6000 Hz) hearing sensitivity than low-frequency hearing sensitivity (f2 < 1000 Hz) (Gorga et al., 2000; Zhao & Stephens, 1999). Low-frequency DPOAE measurements are more vulnerable to ambient noise and body noise than higher frequency measurements. In a laboratory study of DPOAEs in a large sample of ears with normal hearing and ears with hearing loss, it was shown that DPOAEs were not 100 percent accurate at differentiating normal hearing from impaired ears; however, the number of times a diagnosis was incorrect was small for all of the parameters considered (Gorga et al., 1997). The participants of this study were between one year old and 96 years old. DPOAEs were measured with a ratio 1.2 for f2/f1 for the f2 frequencies of 750 to 8000 Hz. The primary levels were f1 = 65 dB and f2 = 55 dB. Results indicated that DPOAEs were most accurate when normal hearing was defined as 20 to 30 dB HL or better than when using more stringent or lax definitions of hearing loss. Smaller DPOAE levels were observed in some individuals with mild hearing losses, but rarely in individuals with greater than minimal hearing loss. Furthermore, DPOAEs performed best for predicting hearing sensitivity in the frequency region of 1500 Hz to 6000 Hz, with the best prediction at 4000 Hz and 6000Hz, compared to poorer performance when predicting hearing sensitivity below 1500 Hz or at 8000 Hz (Gorga et al., 1997). Using multivariate analysis further improved the performance of DPOAEs in predicting hearing loss (Dorn et al., 1998);

however, these statistical measures are not currently available on commercial OAE equipment.

For screening and other clinical purposes, the 2f1-f2 DPOAE is measured by holding the levels of f1 and f2 constant at 65 and 55 dB SPL, respectively, holding the f2/f1 ratio constant at approximately 1.2, and changing the f1 and f2 frequencies. Moderate level primaries are preferred to higher level primaries (above 65 dB SPL) because they are more sensitive in the identification of hearing loss (Stover, Gorga, & Neely, 1996), and because research has shown that people with hearing loss may exhibit measurable emissions at high intensity levels (Moulin, Bera, & Collet, 1994). The difference in primary levels (f1 10 dB higher than f2) and f2/f1 ratio of 1.2 are recommended because research has shown they result in higher 2f1-f2 levels across ears with normal hearing (Gaskill & Brown, 1990).

Results are usually viewed as a "DP-gram." A DP-gram is a graphic representation of the 2f1-f2 DPOAE level and corresponding noise floor levels as a function of each f2 frequency being tested. Although the 2f1-f2 DPOAE occurs at a frequency that is different and lower than the primary frequencies, it is assumed that a measure of cochlear function at f2 is being obtained (Gorga et al., 1997). Research has indicated that the region of overlap between the two traveling waves produced by f1 and f2, close to the f2 place, is likely the primary generation source of the 2f1-f2 DPOAE that is measured in the ear canal (e.g., Martin, Lonsbury-Martin, Probst, Scheinin, & Coats, 1987).

During a hearing screening, DPOAEs are measured for f2 frequencies in the range of 1500 - 6000 Hz. Frequencies lower than 1000-1500 Hz are not tested during

universal newborn hearing screenings due to the ambient noise present in most newborn testing environments (e.g., nurseries) and the poorer performance of DPOAEs in predicting hearing status at these frequencies (e.g., Gorga et al., 1997). DPOAEs are measured from a given ear and compared to the defined passing criteria. A single set of criteria is not established for use in all screening programs; however, a typical example of a passing criterion for a newborn hearing screening is a 6 dB DPOAE/noise floor ratio for three out of five f2 frequencies tested (Hatzopoulos et al., 2001). Software designed for newborn hearing screening applications typically allows the user to program in the passing criteria, so that the equipment will identify a particular DPOAE test as a "pass" or a "fail" to limit interpretation error. If the DPOAEs measured from a particular ear do not meet the passing criteria, that child is considered at risk for hearing loss in that ear and will require further follow-up testing (Norton et al., 2000b).

Screening programs often consist of multiple steps in an attempt to limit false positive and false negative findings. Infants who fail an initial hearing screening in the hospital are often re-screened again before hospital discharge or may be re-screened at a separate appointment within a few weeks of hospital discharge. The multiple attempts at screening help to reduce false positive results in those children who have transient outer or middle ear issues that prevent accurate measurement of OAEs shortly after birth. Transient outer and middle ear problems can include vernix in the ear canal or mesenchyme that has failed to be reabsorbed in the middle ear space (e.g., Eavey, 1993). By allowing some additional time to elapse, these

conditions may resolve on their own, permitting accurate measurement of OAEs and resulting in a passing screening result within the first few weeks of life.

Multiple screenings using both auditory brainstem response (ABR) testing and OAE measurements are aimed at reducing false negatives, because the two tests target function at different levels of the auditory system. Some conditions, such as auditory neuropathy, that may be missed by an OAE screening will result in a failure when using ABR. Additionally, infants who pass an initial screening in the hospital but who are known to have risk factors for later-onset or progressive hearing loss should be re-tested in the future. Once all steps of the screening process are completed, those infants who have failed the multiple screenings are referred for diagnostic testing to determine hearing status.

Body Position and Audiometric Measures

Body position has been shown to affect a number of audiometric measures. It is hypothesized that with changes in posture there are changes in the cerebro-spinal fluid pressure transmitted to the labyrinth via the cochlear aqueduct, resulting in changes in the hydrostatic pressure of the perilymph in the inner ear (Daniel, Hume, Givens & Jordan, 1985; Phillips & Farrell, 1992). This is believed to result in a displacement of the stapes footplate at the oval window, therefore altering the ossicular chain, tympanic membrane, and basilar membrane response characteristics (Phillips & Farrell, 1992). Figure 1 depicts the different body positions reported on in the literature.

Changes in body position can result in changes in auditory thresholds in adults. Corso (1962) evaluated the hearing sensitivity of 20 male college students in

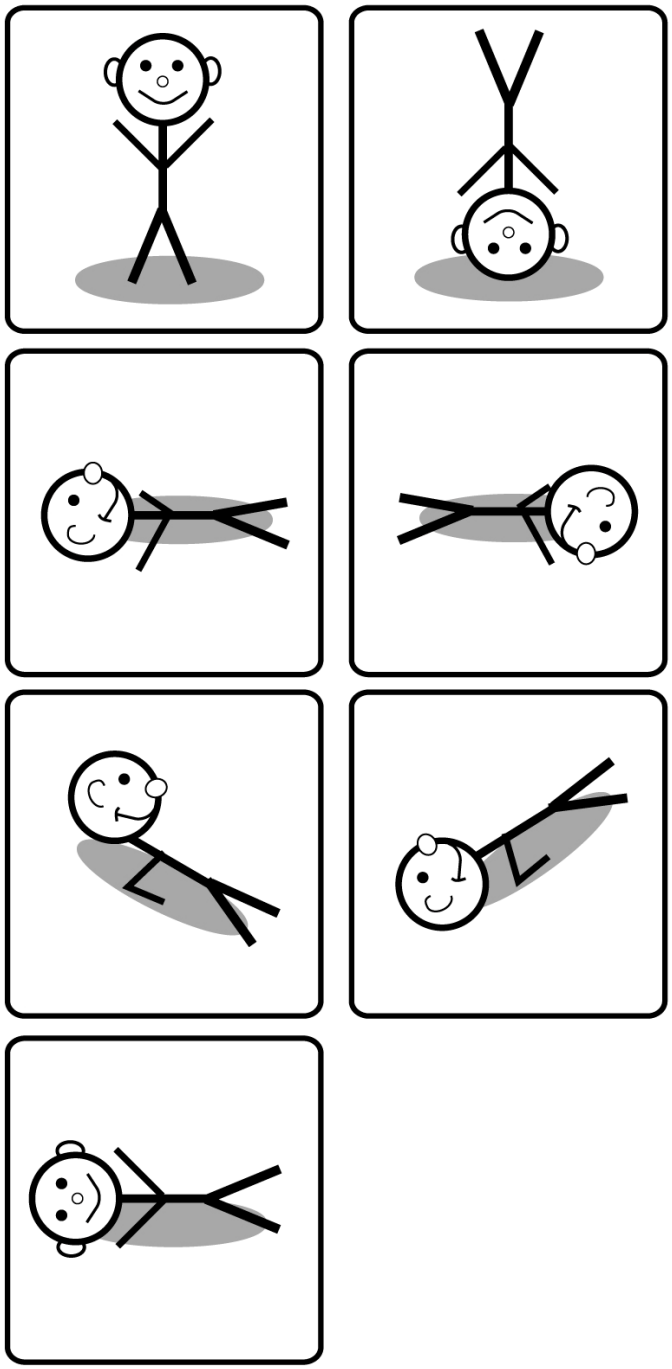

Figure 1: Body positions commonly referred to in the literature on the effect of body position on audiometric measures. Clockwise from the top left: upright, inverted, prone, head-lowered below supine, lying on the side, head-raised above supine, and supine.

ten body positions. The body positions tested included: standing, sitting head-raised, sitting tilted to the right, sitting tilted to the left, sitting tilted backward, sitting tilted forward, lying prone, lying supine, lying on the right side, and lying on the left side. Test order of the body positions and test frequencies were randomized in this study. Corso found that changes of up to 4.5 dB occurred across positions. The greatest differences were noted between the prone and supine body positions, with thresholds poorer in the prone position than the supine position. This study only evaluated the results of three frequencies: 500 Hz, 1500 Hz, and 3000 Hz; however, differences were seen for all three test frequencies (Corso, 1962). Greater differences in hearing sensitivity have been observed in the inverted position with changes of up to a 15 dB increase in auditory threshold (Miltich, 1968; Macrae, 1972). The inverted position is not a position that is clinically relevant, and only the low frequency thresholds of 150 Hz, 250 Hz and 500 Hz were considered for analysis in these other studies.

Another measure that body position is believed to influence is middle ear pressure. Middle ear pressure measured using standard 226 Hz tympanometry increases when body position is changed from an upright position to a recumbent position (Daniel et al., 1985; Macrae, 1972), including the recumbent positions of inverted, supine, prone, and lying on the side with either the test ear down or up. Although an increase in pressure of approximately 13.5 daPa (Daniel et al., 1985) to 22 daPa (Gaihede & Kjaer, 1998) is statistically significant, it is not necessarily clinically relevant and would not be expected necessarily to influence DPOAE measurements. The slight rise in middle ear pressure that has been observed (e.g., Daniel et al., 1985, Gaihede & Kjaer, 1998) when body position is altered from an

upright position to a supine position has been shown to stabilize after 30 seconds in the new position (Gaihede & Kjaer, 1998).

Tideholm and colleagues (1999) evaluated the effects of body position and sleep on middle ear pressure. Middle ear pressure was analyzed over a 24 hour period using custom equipment in 11 adult participants (mean age = 28 years). They concluded that the differences in body position between the recumbent and upright positions were not significant; however, a significant rise in middle ear pressure was observed during sleep (Tideholm, Brattmo, & Carlborg, 1999). It is hypothesized that sleep alters Eustachian tube function; therefore, in studies where measurements occur over a longer period of time, apparent effects of body position may be attributed to the arousal state of the participant and not to the actual body position (Tideholm et al., 1999).

Changes in middle ear pressure with sleep could be particularly salient for testing in newborns, who spend most of the day sleeping. However, obtaining information on middle ear status in newborns has been challenging. There is significant difficulty in measuring middle ear status through conventional tympanometry in newborns. Use of a 226 Hz probe tone results in unpredictable tympanogram morphology in newborns (Schwartz & Schwartz, 1980; Sprague, Wiley, & Goldstein, 1985); therefore, measurement of 226 Hz tympanograms is not appropriate in this population. Because the infant ear canal has not ossified and the infant middle ear system is mass-dominated below 1000 Hz, the use of a higher frequency probe tone, specifically 1000 Hz, is the current recommendation when recording tympanograms in young infants (ASHA, 2007; Holte, Margolis, &

Cavanaugh, 1991; Keefe, Bulen, Arehart, & Burns, 1993; Swanepoel et al., 2007). Although the use of 1000 Hz tympanograms is superior to the use of a lower frequency probe tone in infants for screening for middle ear fluid, reliability remains unpredictable in very young infants (Keefe et al., 1993; Kei et al., 2003). Developmental changes are seen in 1000 Hz tympanometry up to four to six months of age (Abdala & Keefe, 2006; Holte et al., 1991). Further confounding middle ear measurements in newborns shortly after birth is the presence of mesenchyme, amniotic fluid and other debris in the outer and middle ears of infants (Eavey, 1993). Likely due to the significant difficulty measuring middle ear status in infants, there is no research available to support an effect of body position on middle ear pressure/status in infants.

Body Position and OAEs

One non-pathological influence on OAEs that has not been investigated in infants is the effect of body position. This is an important consideration because clinical OAE testing is conducted in many different body positions (e.g., supine, lying on the side, etc.), particularly in newborns. Changes in OAE levels with changes in body position have been reported in adults for SOAEs, TEOAEs, and DPOAEs.

SOAE levels change when adults are shifted from the upright position to a recumbent position with the head lowered below supine and then to the upright position again (de Kleine, Wit, van Dijk, & Avan, 2000). de Kleine et al. (2000) tested 14 ears, each with at least one measurable SOAE. The number of participants and the age range of participants were not indicated by the authors of this study. Changes were seen during postural changes in all of the ears tested. An increase in

peak frequency and a decrease in amplitude of the SOAE were reported when the participant was moved from the upright position to the recumbent position with the head lowered 30 degrees below supine. The frequency and amplitude returned to their original values when the participant was returned to the upright position (de Kleine et al., 2000). The greatest differences were noted at frequencies less than 2000 Hz. The basis of the change was hypothesized to be an increase of intracochlear fluid pressure resulting in stiffening of the cochlear windows between the upright and recumbent positions (de Kleine et al., 2000). Although SOAEs are not measured clinically, the presence of SOAEs has been shown to affect the amplitude of evoked otoacoustic emissions (Prieve et al. 1997). Therefore, changes in SOAEs with body position could result in differences in evoked OAE levels in different body positions. However, the only body positions that were evaluated in this study were upright and the recumbent position of head lowered 30 degrees below supine. In a clinical setting, it is unlikely that OAEs would be measured with a patient in this recumbent body position. Another concern is that the authors of this study do not indicate that differences/changes in probe fit were accounted for during postural changes.

A difference in TEOAEs measured using clicks also has been reported when body position changed from the upright position to the position with the head lowered 30 degrees below supine (de Kleine et al., 2001). In this study, TEOAE measurements were recorded during stationary and dynamic body position changes in a group of nine males and 19 females with normal hearing sensitivity between the ages of 19-35 years. The change from an upright to the lowered position resulted in a decrease in TEOAE level for test frequencies below 2000 Hz. The authors reported a

time period of 30 seconds was needed to regain stability following lowering the head and a time period of 20 seconds was needed to regain phase and amplitude stability after raising the head (de Kleine et al., 2001). Similar to their study of SOAEs, only one of the two body positions that de Kleine et al. (2001) evaluated (upright) is clinically relevant/practical.

Phillips and Farrell (1992) evaluated differences in tympanic membrane displacement and in TEOAEs for changes between sitting and the head lowered 40 degrees below supine. The participants were six normal hearing adults between the ages of 23 and 40 years old. Tympanic membrane displacement was measured by eliciting the stapedius muscle reflex, such that the magnitude and the direction of the reflex were evaluated as an indication of the cochlear fluid pressure at the stapes footplate. Changes in the cochlear fluid pressure resulted in changes in the morphology of the measured reflex. TEOAE measurements were made using a 70 dB SPL click stimulus. Significant differences were observed in both TEOAEs and tympanic membrane displacement during postural changes; however, statistical analysis revealed no significant correlation between the two measurements. This finding suggests that although changes are occurring in both the middle ear and the inner ear in response to postural changes, they are independent of each other (Phillips & Farrell, 1992).

Voss et al. (2006) investigated the use of postural-induced changes in DPOAEs as a means of measuring intracranial pressure in a group of seven adult females aged 19-36 years. The body positions tested included upright, supine, 30 degrees below supine, and 45 degrees below supine. Results indicated that DPOAE

level significantly decreased as posture was moved from upright to 45 degrees below supine. Differences in DPOAEs induced by postural changes were most evident for f2 frequencies below 1500-2000 Hz (Voss et al., 2006). This study only had seven participants, and the results do not support a clinically significant change in DPOAE level for hearing screening purposes as the significant differences were only present for low frequency emissions (less than 2000 Hz). Furthermore, the test positions of 30 degrees and 45 degrees below supine are not clinically relevant.

Driscoll et al. (2004) reported on effects of body position that would be clinically relevant in their study of DPOAE amplitude, DPOAE/noise, and noise levels in 120 ears of 60 normal-hearing adults (mean age = 26 years). The positions tested in this study were lying on the side ("one-sided"), supine, and seated (upright). A 30 second time interval was included between testing in each body position to allow the emissions to stabilize. Testing was conducted a total of three times in each body position. DPOAEs were recorded with levels of 65 dB SPL and 55 dB SPL for f1 and f2, respectively, for f2 frequencies of 1000 to 6300 Hz.

Driscoll et al. (2004) found that when conducting testing in the one-sided position, stronger emissions were observed than when testing was conducted in the seated and supine body positions; this was found to be statistically significant for the mid frequencies tested (1500, 2000, 2500, and 3100 Hz). There were no significant differences in DPOAE amplitude noted between the seated and supine body positions. Significantly higher noise floor levels were observed for certain frequencies when testing in the one-sided position compared to either of the other two body positions used in this study (1000, 1200, 1500, 5000, and 6300 Hz). The supine position

resulted in the lowest overall noise floor levels when compared to the one-sided and seated body positions (Driscoll et al., 2004). This study failed to find a significant difference between genders or ears for any of the test parameters.

The authors of this study conclude that it is important to consider body position when conducting OAE testing in a clinical setting (Driscoll et al., 2004). The authors suggest that future research be done to look at how body position affects test sensitivity and specificity, and recommend that normative data be developed to account for body position influences on measurement parameters. All three of the body positions investigated in the Driscoll et al. study are positions that are utilized clinically; however, the order of positions used was not randomized, which may have resulted in order effects.

Summary and Purpose

Existing literature indicates effects of body position on OAE levels and noise floor levels in adults (e.g., de Kleine at al., 2000, 2001; Driscoll et al., 2004; Phillips & Farrell, 1992; Voss et al., 2006). The OAE level effects were greatest for low frequency emissions (<2000 Hz) (de Kleine et al., 2000, 2001; Driscoll et al., 2004; Voss et al., 2006), although the effects of body position on noise floor impacted all frequency regions (Driscoll et al., 2004). These findings have potential implications for hearing screenings in neonates. There have been no studies examining the effects of body position on OAEs in infants, despite the fact that newborns are one of the primary populations for whom OAE testing is used. OAEs are utilized routinely in newborn hearing screening programs, and any effects of body position on OAE measurements should be considered during OAE testing in this population.

The current study investigated the effect of body position on DPOAE testing in neonates. DPOAE levels, noise floor levels, DPOAE/noise levels (difference between the DPOAE level and noise floor level), test time, and pass/fail rates were compared for three body positions: lying on the left side ("one-sided"), supine, and with the head elevated 45 degrees above supine ("head-raised"). The ultimate goal of this study is to determine if there is an optimal body position for newborn hearing screening, specifically, if there is a body position for which test time is shorter and the sensitivity and specificity of DPOAEs as a hearing screening tool are improved. Data also were analyzed for effects of gender and frequency.

Chapter 3: Experimental Questions and Hypotheses

The goal of this study was to determine if there is an effect of body position on DPOAE measurements and screening outcomes in neonates. DPOAE screenings were conducted on neonates in three body positions: lying on the left side (right ear up; "one-sided"), supine, and head raised 45 degrees above supine ("head-raised"). The data was analyzed to answer the following questions:

1. Does body position affect the DPOAE level measured during DPOAE screenings of neonates?

    Hypothesis: Body position was expected to affect DPOAE level. It was hypothesized that the DPOAE amplitude would be largest in the one-sided position (lying on the left side) when compared with the other two body positions, similar to the findings of Driscoll, et al. (2004) in adults.

2. Does body position affect noise floor levels measured during DPOAE screenings of neonates?

    Hypothesis: Body position was expected to affect noise floor levels during DPOAE hearing screenings. It was hypothesized that the noise floor level would be higher in the one-sided body position compared to the other two body positions (Driscoll et al., 2004). Lower noise floor levels were expected in the supine body position compared to the other two body positions (Driscoll et al., 2004). It was expected that differences in noise floor level would be small as Driscoll et al. (2004) reported an overall difference of less than 3 dB.

3. Does body position affect the DPOAE/noise (difference between the DPOAE level and noise floor level) measured during DPOAE screenings of neonates?

Hypothesis: Body position was expected to affect DPOAE/noise. It was hypothesized that the DPOAE/noise would be largest in the one-sided position when compared with the other two body positions. Driscoll et al. (2004) found differences in both amplitude and noise in adults such that both were higher in the one-sided position; however, the overall differences in the noise floor were small. Therefore, DPOAE/noise was expected to be highest in the one-sided body position.

4. Does body position affect the amount of time it takes to complete the DPOAE test in newborn hearing screenings?

Hypothesis: Body position was expected to affect the amount of time it takes for testing in newborn hearing screenings. It was hypothesized that the DPOAE amplitude would be highest in the one-sided body position resulting in a shorter test time than the other body positions (Driscoll et al., 2004). With higher DPOAE amplitudes in the one-sided body position the participants were expected to achieve the stopping criteria for each test frequency more quickly than the other two body positions.

5. Does body position affect the pass/fail rate in newborn hearing screenings?

Hypothesis: Body position will affect the pass/fail rate in newborn hearing screenings. It is hypothesized that the pass rate would be the highest in the one-sided body position due to larger DPOAE amplitudes compared to the amplitudes obtained in the other two body positions (Driscoll et al., 2004). Although, the noise floor level was expected to be higher in the one-sided position this difference was expected to be small (less than 3 dB)

compared to the other two body positions (Driscoll et al., 2004). A pass for each frequency was determined by the DPOAE/noise which was expected to be higher for the one-sided body position.

6. Are there gender differences associated with DPOAE newborn hearing screenings conducted in different body positions?

Hypothesis: Females were expected to have larger DPOAE levels than males in all positions (Cacace et al., 1996; Gaskill & Brown, 1990). It was hypothesized that the differences observed in DPOAE level between males and females would be small and not clinically significant. Furthermore, no differences were expected to be observed in the noise floor levels present for males and females. There was no interaction expected between gender and body position.

7. Are frequency effects present when conducting DPOAE screenings in different body positions?

Hypothesis: It was hypothesized that the greatest differences in DPOAE levels and in noise floor levels between the three body positions would be observed for 1500 Hz and 2000 Hz. This has been shown in other studies, although Driscoll and colleagues found frequency effects across the range of frequencies (1000-6300 Hz) for the various parameters studied. Low frequency stimuli (<2000 Hz) are more vulnerable to ambient noise, and noise floor levels were expected to be relatively high in a newborn nursery compared to more controlled clinic/research environments (e.g., clinic examination rooms, sound-proof booths).

Chapter 4: Method

IRB approval was obtained from Washington Hospital Center and the University of Maryland, College Park for this study. Consent forms are included in Appendix A and B.

Participants

Participants were 47 newborns recruited from a pool of infants in the well-baby nursery who passed a newborn hearing screening at Washington Hospital Center, in Washington, DC between December 2007 and March 2008. There were 25 female participants and 22 male participants. Thirty-three of the participants were delivered vaginally, and 14 of the participants were delivered through cesarean section. The majority of the participants were African American (n = 42), four participants were Caucasian, and one participant was Asian. All infants were tested within the first 14 to 63 hours of life with a mean age of 33 hours since birth (SD = 12 hours).

Recruitment was accomplished by speaking in person with the parent of each neonate who met the inclusion criterion. All participants were full-term infants (38 weeks gestational age or older) with no risk factors for hearing loss. Risk factors for hearing loss include a family history of hereditary childhood sensorineural hearing loss, craniofacial anomalies, low birth weight (less than 1500 grams), exposure to ototoxic medications, congenital infection, low Apgar scores (0-4 at one minute or 0-6 at five minutes), use of mechanical ventilation, or stigmata for a known disorder associated with hearing loss (Vohr et al., 2000). Each infant had an unremarkable

physical examination by a neonatologist. Infants with risk factors for hearing loss and those with remarkable physical exams were excluded to minimize extrinsic factors influencing the screening measurements for each infant.

Equipment and Stimuli

DPOAE testing and analysis were conducted using the Bio-logic Scout Sport Diagnostic OAE system version 3.45.i01 connected to a Hewlett Packard laptop computer. The equipment is calibrated annually in December. Disposable ear probe tips were utilized for testing. All measurement parameters utilized for this study were similar to those currently used by the Washington Hospital Center's universal newborn hearing screening program with the addition of the test frequency of 1500 Hz. Other universal newborn hearing screening programs have used a similar protocol (e. g., Norton et al., 2000b).

The DPOAE primaries were presented at f1 = 65 dB SPL and f2 = 55 dB SPL. The frequency ratio (f2/f1) was 1.22. Test frequencies for f2 were 1500, 2000, 3000, 4000, and 6000 Hz presented in order of descending frequency. DPOAEs have been shown to be most sensitive at identifying hearing loss for the 2000-6000 Hz region (e.g., Gorga et al., 1997). Frequencies lower than 1500 Hz are not typically tested during universal newborn hearing screenings due to the ambient noise present in most newborn testing environments (e.g., nurseries). Sound level measurements obtained in the nursery on five different days of testing indicated an average ambient noise level of approximately 60 dB SPL (*SD* = 7.99 dB).

The emission at 2f1-f2 was analyzed. Measurements included the DPOAE level, noise floor level, DPOAE/noise (difference between the DPOAE level and

noise floor level), the time needed to complete the test, and the outcome of the screening measure (pass/fail).

The equipment automatically stopped collecting data at each f2 frequency when certain criteria were met. Each data point at the various f2 frequencies was the average of a minimum of 1024 sweeps before the stopping criteria were employed. Once the minimum number of averages was collected, data collection at each f2 frequency was halted if any of the following stopping criteria were met: (1) DPOAE amplitude was greater than -5 dB with a noise floor of -17 dB or lower, OR (2) DPOAE/noise was 8 dB or greater, OR (3) the time for data collection exceeded 20 seconds. These stopping criteria were chosen because they are used at the Washington Hospital Center for newborn hearing screenings.

The time it took to complete each test was recorded by the Bio-logic DPOAE measurement equipment. The recorded time includes the time it took to complete the test collection after an appropriate probe fit had been achieved and checked by the equipment. An acceptable probe fit indicated that stimulus levels were accurate and that noise floor levels in the ear canal were satisfactory. The decision as to whether a probe fit was acceptable was made automatically by the Biologic Scout software. A passing screening result was defined as DPOAE amplitude of at least 6 dB over the noise floor level for three of the five test frequencies.

Procedures

All testing took place at Washington Hospital Center's well-baby nursery in the afternoon between 1:00 pm and 5:00 pm. This environment was chosen because it is commonplace for newborn hearing screenings to be conducted in the hospital

nursery. DPOAEs were measured and analyzed for the right ear only in three body positions: lying on the left side ("one-sided"), supine, and head raised 45 degrees above supine ("head-raised"). These test positions were chosen because they are common positions for infants to be placed in during testing. All testing was done with the infant lying in their crib. The cribs used in the hospital nursery can be adjusted for the infants to lie in a supine body position or so the head is raised 45 degrees above their feet. The order of positions was counter balanced across participants with the order of the three positions for each participant used during the first set of three trials reversed for the second set of three trials (e.g., one-sided, supine, head-raised, head-raised, supine, one-sided).

Because probe fit is the main contributor to the short-term and long-term variability of measured emissions (Beattie et al., 2003; Wagner et al., 2008; Zhao & Stephens, 1999), the probe was removed and replaced prior to each measurement, and testing was conducted twice in each body position. The average of two tests obtained in each body position was used in analyses. The equipment performed a probe fit check prior to each test run to ensure that an appropriate fit was maintained and that the noise floor level in the ear canal was at an acceptable level to perform the test. The time interval between the testing of each position was 30 seconds measured with a stop-watch; this was to ensure that the emissions from the previous DPOAE test had stabilized (de Kleine et al., 2001) and that middle ear status had stabilized (Gaihede & Kjaer, 1998). The average test time, including set-up, was 15 minutes per infant, with approximately two minutes per DPOAE test (set-up and collection).

Data Analysis

All statistical analyses were completed using SPSS version 14. As stated previously, the values used for statistical analysis were the average of two test runs in each body position. To evaluate whether body position impacts the dependent variable of DPOAE level, data were analyzed using a three-way, mixed-model ANOVA. Gender was a two level (males and females) between-subjects factor, body position was a three level (one-sided, supine, and head-raised) within-subjects factor, and frequency was a five level (1500, 2000, 3000, 4000, 6000 Hz) within-subjects factor. Three-way, mixed-model ANOVAs with the same between-subjects factor and the same within-subjects factors were also utilized to evaluate the impact of the dependent variables of noise floor level and DPOAE/noise. For the dependent variable of test time, a two-way, mixed model ANOVA was used with the factors of gender (two levels, between-subjects) and body position (three levels, within-subjects). For the dependent variable of screening outcome a Chi-square test was used with the factors of body position (three levels) and screening outcome (pass or refer).

When violations of sphericity were indicated by Mauchly's Test of Sphericity, the Greenhouse-Geiser correction was utilized. The alpha level of .05 was corrected using the Bonferroni adjustment where indicated. Where initial analysis revealed a significant main effect, a Tukey post-hoc analysis was utilized for pair-wise comparisons.

Test-Retest Variability

Testing was conducted two times in each body position. The probe was removed and then replaced between each test run. The mean difference in DPOAE level between tests one and two obtained in each of the three body positions for each of the five f2 frequencies is shown in Figure 2. The top panel presents data for the female participants, and the bottom panel presents data for the male participants. The error bars represent one standard deviation from the mean. In general, the difference in DPOAE level decreased with an increase in f2 frequency, although this trend is more notable for the male participants. No consistent differences in the variability of DPOAE level are noted between the three body positions tested. The mean difference in DPOAE level between the two test runs ranged from 2.0 dB and 4.8 dB (*SDs* = 1.7 – 5.9 dB). Literature indicates the within-subjects test-retest variability of DPOAEs is within 5 dB between test runs in normal-hearing adult participants (Beattie et al., 2003).

For analysis of DPOAE level variability, a three-way mixed-model ANOVA was utilized with the within-subject variables of body position (three levels: one-sided, supine, head-raised) and frequency (five levels: 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, and 6000 Hz) and the between-subjects variable of gender (two levels: males and females). The main effect of body position was not significant, F (2, 88) = .212, p = .809. The main effect of gender was not significant, F (1, 44) = 1.134, p = .293. The main effect of frequency was significant, F (2.950, 129.822) = 3.692, p = .014. The interaction between position and gender was not significant, F (2, 88) = .104, p = .901. The interaction between frequency and gender was not significant, F

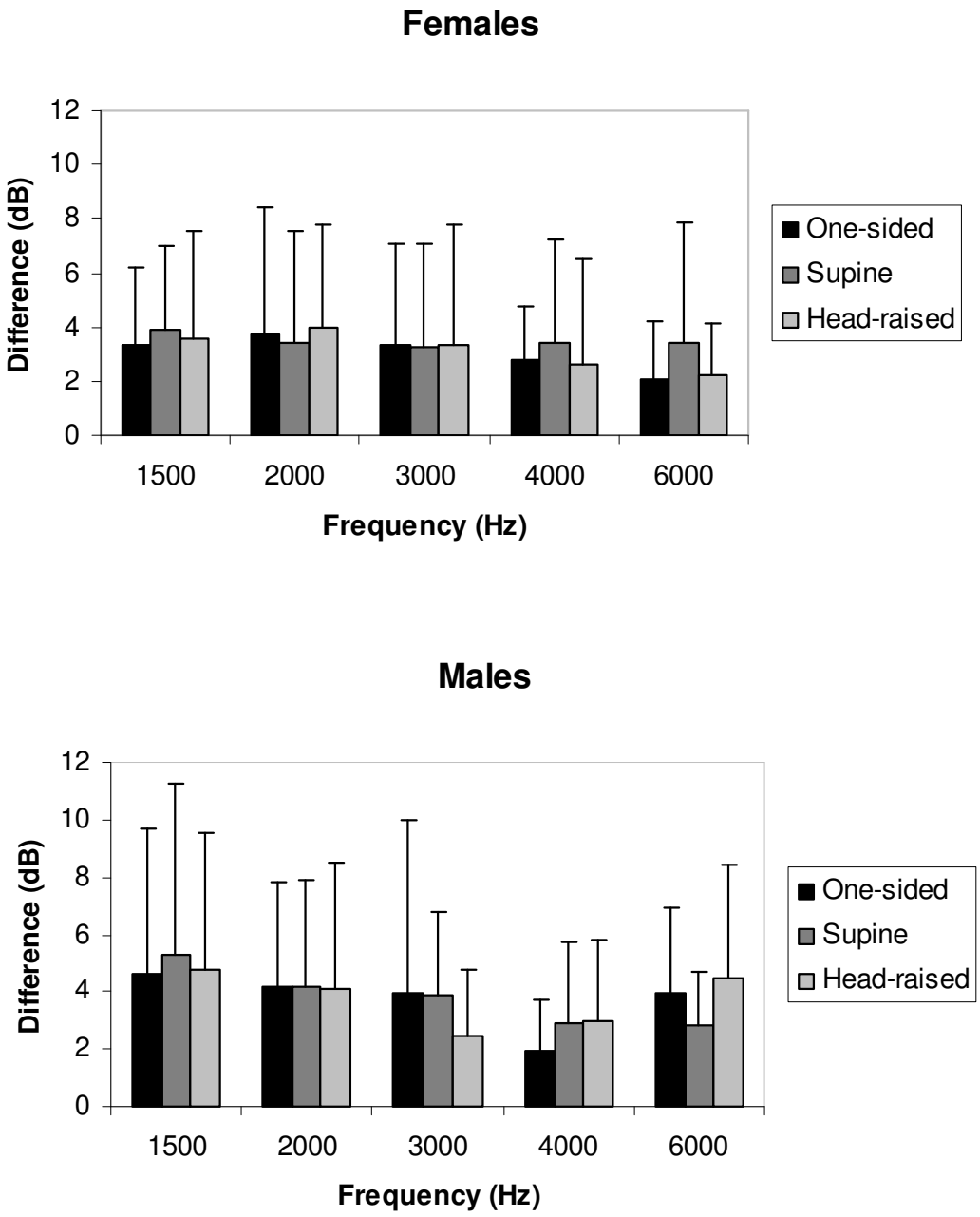

Figure 2. Mean difference in DPOAE level (DP) for female participants (top panel) and male participants (bottom panel) between the two measurements collected in each body position. The probe was refit between the two measurements. Error bars represent one standard deviation from the mean.

(2.950, 129.882) = 1.244, p = .296. The interaction of position and frequency was not significant, F (5.9, 259.603) = .433, p = .854. The three-way interaction between position, frequency, and gender was not significant, F (5.9, 259.603) = 1.046, p = .395. Follow-up testing for the significant main effect of frequency was completed using paired sample t-tests. The Bonferroni correction was utilized; therefore, $p <$ 0.005 was required for a difference to be considered significant. Variability in DPOAE levels at the various f2 frequencies were not significantly different from one another with the exception of the paired frequencies of 4000 Hz and 2000 Hz (p =.002) and 4000 Hz and 1500 Hz (p = .001).

Figure 3 represents the mean difference in noise floor level between test runs for the three body positions at each frequency. The top panel presents data for the female participants, and the bottom panel presents data for the male participants. The error bars in Figure 3 represent one standard deviation from the mean. No consistent differences in the variability of the DPOAE noise floor level are noted between the three body positions for either gender. The mean difference in the noise floor level between the two tests obtained in each body position is similar for all five test frequencies and ranged between 2.7 dB to 6.4 dB (*SDs* = 2.1 – 6.4 dB).

For analysis of DPOAE noise floor level variability, a three-way mixed-model ANOVA was utilized with the within-subject variables of body position (three levels) and frequency (five levels) and the between-subjects variable of gender (two levels). The main effect of body position was not significant, F (2, 88) = .719, p = .490. The main effect of gender was not significant, F (1, 44) = 1.742, p = .194. The main

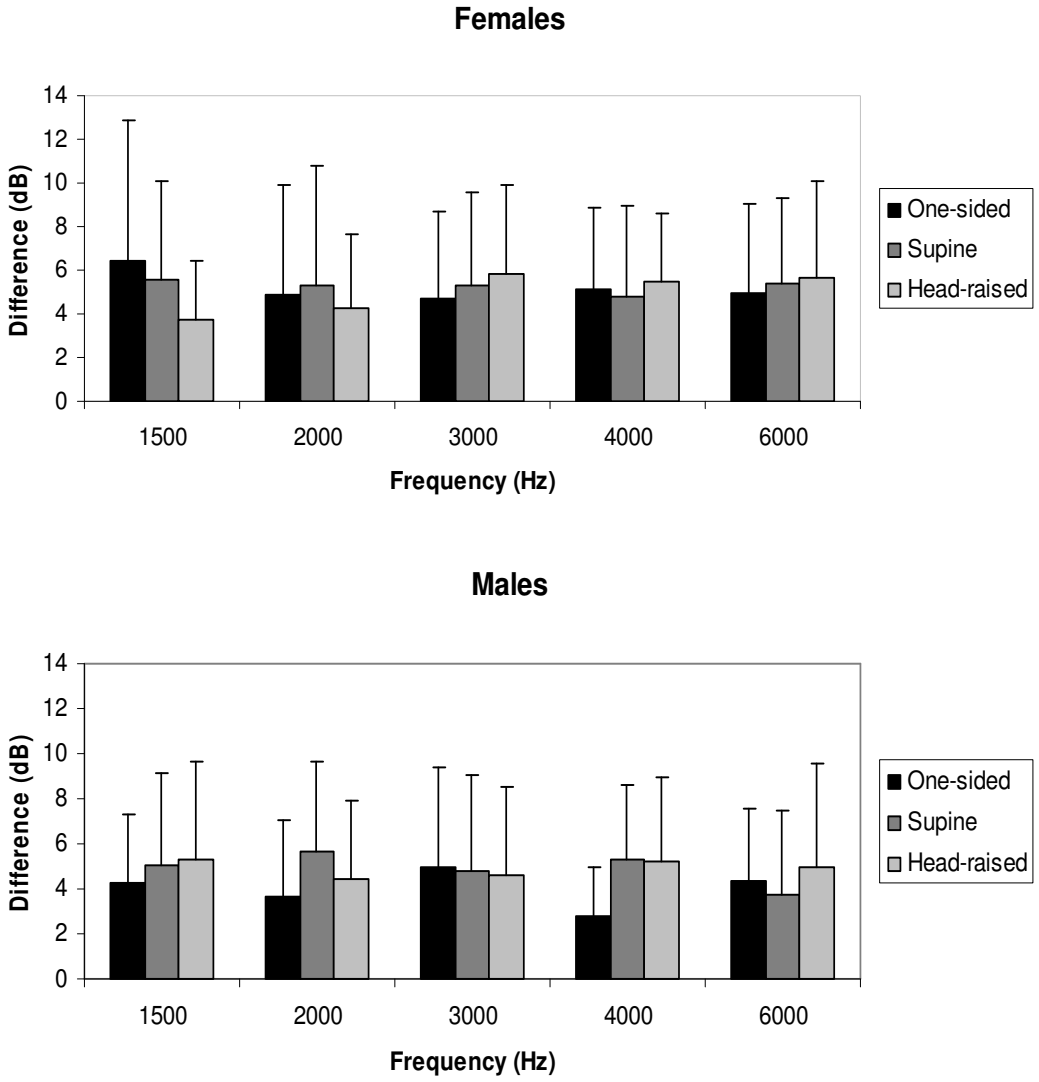

Figure 3. Mean difference in noise floor level (NF) for females (top panel) and males (bottom panel) between the two measurements collected in each body position. The probe was refit between each measurement. Error bars represent one standard deviation from the mean.

effect of frequency was not significant, F (4, 176) = 1.88, p = .944. The interaction between position and gender was not significant, F (2, 88) = 1.079, p = .344. The interaction between frequency and gender was not significant, F (4, 176) = .160, p = .958. The interaction of position and frequency was not significant, F (8, 352) = .942, p = .482. The three-way interaction between position, frequency, and gender was not significant, F (8, 352) = 1.229, p = .281.

Chapter 5: Results

DPOAE Level

Individual DPOAE levels measured from the neonate participants ranged from -23.1 to 27.1 dB SPL. The range of DPOAE levels for the female and male neonates as a function of f2 frequency across all body positions are listed in Table 1. Analysis of individual results (not shown) revealed no consistent pattern in the differences in DPOAE levels obtained in the three different body positions.

Mean DPOAE and noise floor levels as a function of f2 frequency for each body position are shown in Figure 4. The top panel displays data for the female participants, and the bottom panel displays data for the male participants. Error bars represent one standard deviation from the mean. DPOAE levels are similar for the three body positions. In general, as the frequency of f2 increases, DPOAE level decreases. DPOAE level appears to be higher in females than males for the five frequencies tested in all three body positions.

For statistical analysis of possible effects on DPOAE level, a three-way mixed-model ANOVA was utilized with the within-subject variables of body position (three levels: one-sided, supine, head-raised) and frequency (five levels: 1500 Hz, 2000 Hz, 3000 Hz, 4000 Hz, and 6000 Hz) and the between-subjects variable of gender (two levels: males and females). The main effect of body position was not significant, F (2, 90) = 1.228, p = .298. The main effect of gender was not significant, F (1, 45) = 3.284, p = .077. The main effect of frequency was significant, F (3.032, 136.423) = 42.355, p = .0001. The interaction between body position and

Table 1. Range of DPOAE levels in dB SPL for female and male neonate participants as a function of f2 frequency.

Gender	1500 Hz	2000 Hz	3000 Hz	4000 Hz	6000 Hz
Females	-7.4 – 27.1	-5.7 – 18.2	-11.9 – 19.2	-6.4 – 19.1	-23.1 – 11.7
Males	-5.5 – 21.3	-18.3 – 21.5	-16.0 - 15.5	-15.5 – 16.5	-14.5 – 9.2

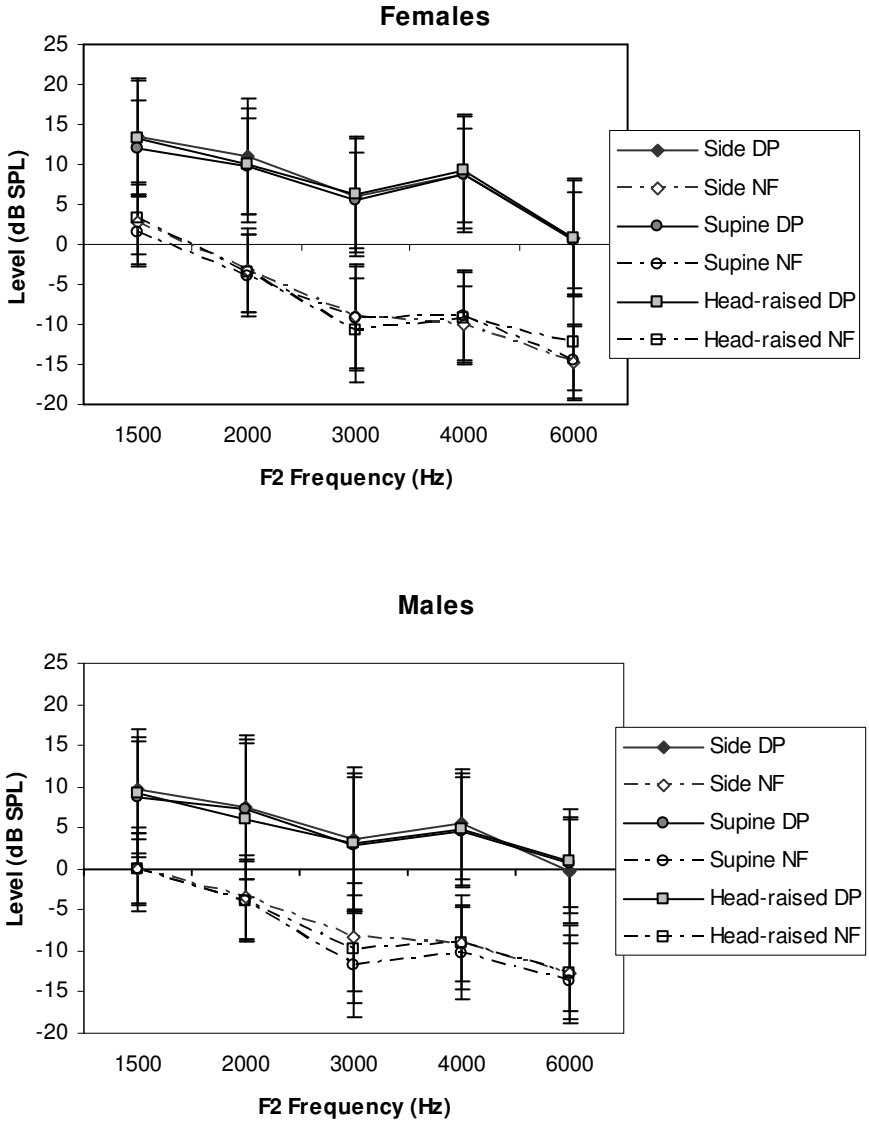

Figure 4. The mean DPOAE level (DP) and noise floor level (NF) for female participants (top panel) and male participants (bottom panel) in three body positions as a function of f2 frequency. Error bars represent one standard deviation from the mean.

gender was not significant, F (2, 90) = .355, p = .702. The interaction between frequency and gender was not significant, F (3.032, 136.423) = 1.447, p = .232. The interaction of body position and frequency was not significant, F (5.593, 251.668) = 1.468, p = .194. The three-way interaction between body position, frequency, and gender was not significant, F (5.593, 251.668) = .773, p = .583.

Figure 5 displays DPOAE level as a function of f2 frequency collapsed across the three body positions and gender. Follow-up testing for the significant main effect of frequency was completed using paired sample t-tests. The Bonferroni correction was utilized; therefore, $p < 0.005$ was required for a difference to be considered significant. DPOAE levels at the various f2 frequencies were all significantly different from one another with the exception of the paired frequencies of 4000 Hz and 2000 Hz (p =.055). Results of the post-hoc t-test analysis are summarized in Table 2.

Noise floor Level

Analysis of individual results (not shown) revealed no consistent pattern of differences between the noise floor measurements obtained in the three body positions. The mean noise floor levels for females (top panel) and males (bottom panel) in each body position as a function of f2 frequency are shown in Figure 4. The error bars represent one standard deviation from the mean. For the most part, noise floor levels were similar across body positions and between genders at all f2 frequencies. The mean noise floor appears to be slightly higher at 1500 Hz in females compared to males, and small differences between body positions are noted at 3000

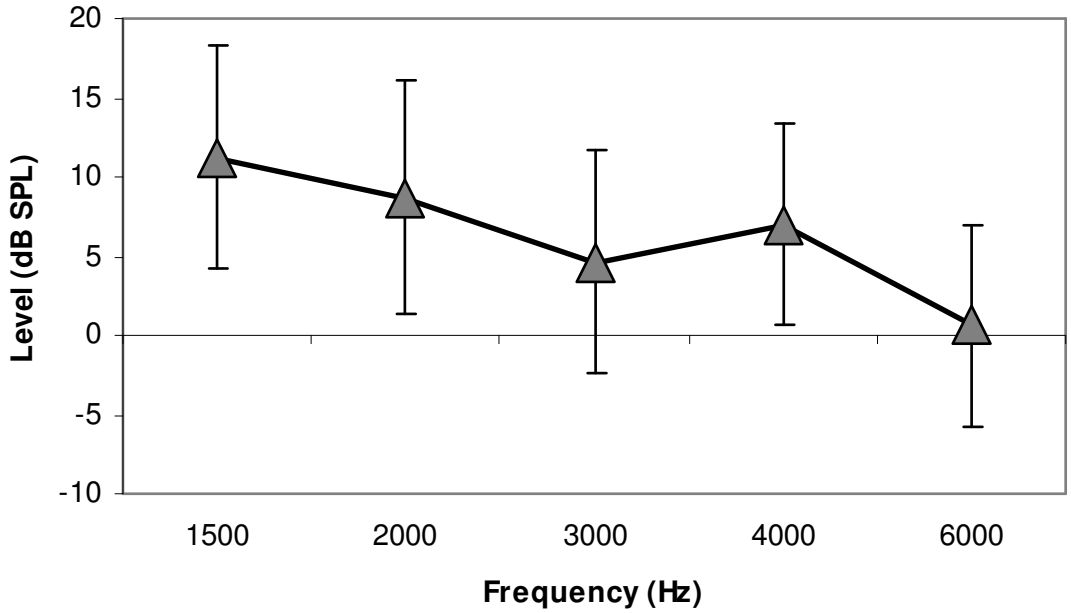

Figure 5. The mean DPOAE level at each frequency collapsed across body position and gender. Error bars represent one standard deviation from the mean.

Table 2. Results of the post-hoc paired sample t-tests to examine the main effect of frequency on DPOAE level.

Paired Frequencies (Hz)	***T***	***df***	***P***
6000 and 4000	-9.287	46	*0.0001
6000 and 3000	-4.608	46	*0.0001
6000 and 2000	-8.408	46	*0.0001
6000 and 1500	-10.038	46	*0.0001
4000 and 3000	3.461	46	*0.001
4000 and 2000	-19.65	46	0.055
4000 and 1500	-4.204	46	*0.0001
3000 and 2000	-5.319	46	*0.0001
3000 and 1500	-6.666	46	*0.0001
2000 and 1500	-3.304	46	*0.002

Note. The alpha level of .05 was corrected using the Bonferroni adjustment by dividing the number of comparisons that were performed in the paired sample t-test, which resulted in $*p < .005$.

Hz in the male participants. In general, as f2 increases, the noise floor level decreases.

A three-way mixed-model ANOVA was utilized to evaluate the effect of the within-subjects factors of body position and frequency and the between-subjects factor of gender on the dependent variable of noise floor level. The main effect of body position was not significant, F (2, 90) = 1.29, p = .280. The main effect of gender was not significant, F (1, 45) = .209, p = .649. The main effect of frequency was significant, F (3.050, 137, 238) = 177.936, p = .0001. The interaction of body position and gender was not significant, F (2, 90) = .602, p = .550. The interaction of frequency and gender was not significant, F (3.050, 137.238) = 1.99, p = .117. The interaction of body position and frequency was not significant, F (6.353, 285.882) = 1.752, p = .105. The three-way interaction of body position, frequency, and gender was not significant, F (6.353, 285.882) = 2.019, p = .059.

Figure 6 displays noise floor level as a function of frequency collapsed across the three body positions and gender. Follow-up testing for the significant main effect of frequency was completed using paired sample t-tests. The Bonferroni correction was utilized; therefore, $p < 0.005$ was required for a difference to be considered significant. Noise floor levels at the various f2 frequencies were all significantly different from one another with the exception of the paired frequencies of 4000 Hz and 3000 Hz (p =.277). Results of the post-hoc t-test analysis are summarized in Table 3.

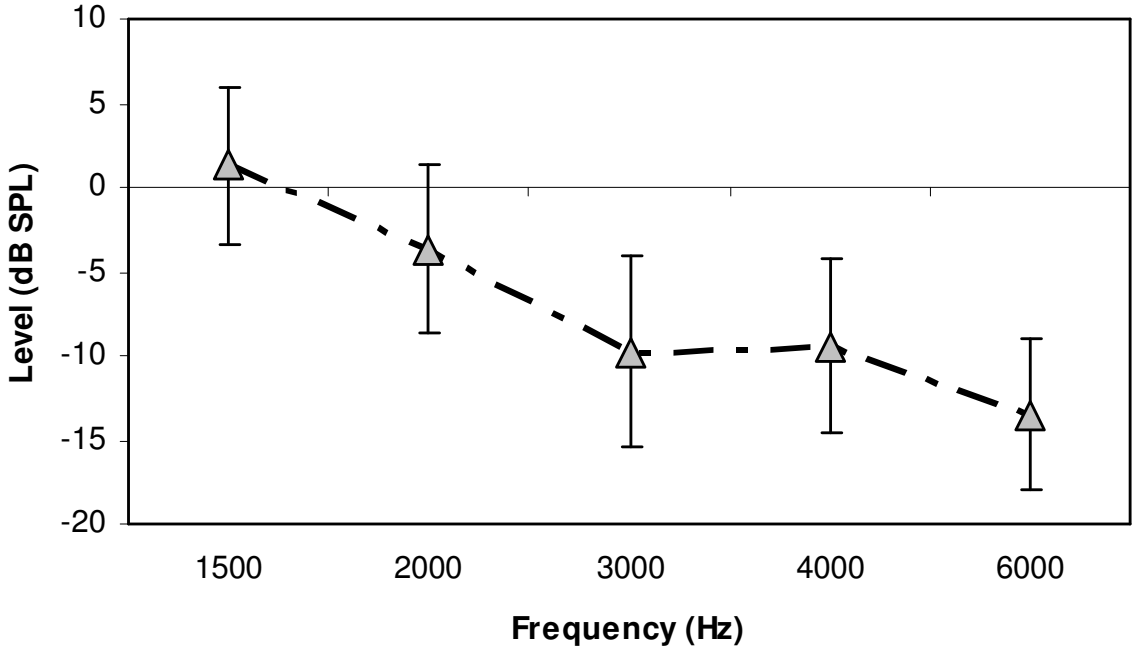

Figure 6. The mean noise floor level for each frequency collapsed across gender and body position. The error bars represent one standard deviation from the mean.

Table 3. Results of post-hoc paired t-tests to examine the main effect of frequency on noise floor level.

Paired Frequencies (Hz)	***T***	***Df***	***p***
6000 and 4000	-9.157	46	*0.0001
6000 and 3000	-7.161	46	*0.0001
6000 and 2000	-18.196	46	*0.0001
6000 and 1500	-22.141	46	*0.0001
4000 and 3000	.724	46	0.473
4000 and 2000	-9.127	46	*0.0001
4000 and 1500	-14.165	46	*0.0001
3000 and 2000	-12.284	46	*0.0001
3000 and 1500	-14.041	46	*0.0001
2000 and 1500	-6.880	46	*0.0001

Note. The alpha level of .05 was corrected using the Bonferroni adjustment by dividing the number of comparisons that were performed in the paired sample t-test, which resulted in *p < .005.

DPOAE/Noise

Figure 7 displays the DPOAE/noise (difference between the DPOAE level and the noise floor; DP – NF) for both males and females in each body position. Each panel depicts data for a different f2 frequency. Error bars represent one standard deviation from the mean. Body position does not appear to impact DPOAE/noise levels within either gender. Mean data appear to indicate slightly higher DPOAE/noise levels for females compared to males at f2 frequencies of 2000 and 4000 Hz. The DPOAE/noise levels are greatest for measurements at 4000 Hz and smallest at 1500 Hz.

A three-way mixed model ANOVA was utilized to determine if any observed trends were significant. The main effect of body position was not significant, F (2, 90) =.806, p = .450. The main effect of gender was not significant, F (1, 45) = 3.042, p = .088. The main effect of frequency was significant, F (3.003, 135.144) = 17.681, p = .0001. The interaction of body position and gender was not significant, F (2, 90) = .341, p = .712. The interaction of frequency and gender was not significant, F (3.003, 135.144) = .933, p =.427. The interaction of body position and frequency was not significant, F (8, 360) = 1.257, p = .265. The three way interaction between body position, frequency and gender was not significant, F (8, 360) = 1.891, p = .060.

Figure 8 displays DPOAE/noise as a function of frequency collapsed across the three body positions and gender. Follow-up testing for the significant main effect of frequency was completed using paired sample t-tests. The Bonferroni correction was utilized; therefore, $p < 0.005$ was required for a difference to be considered

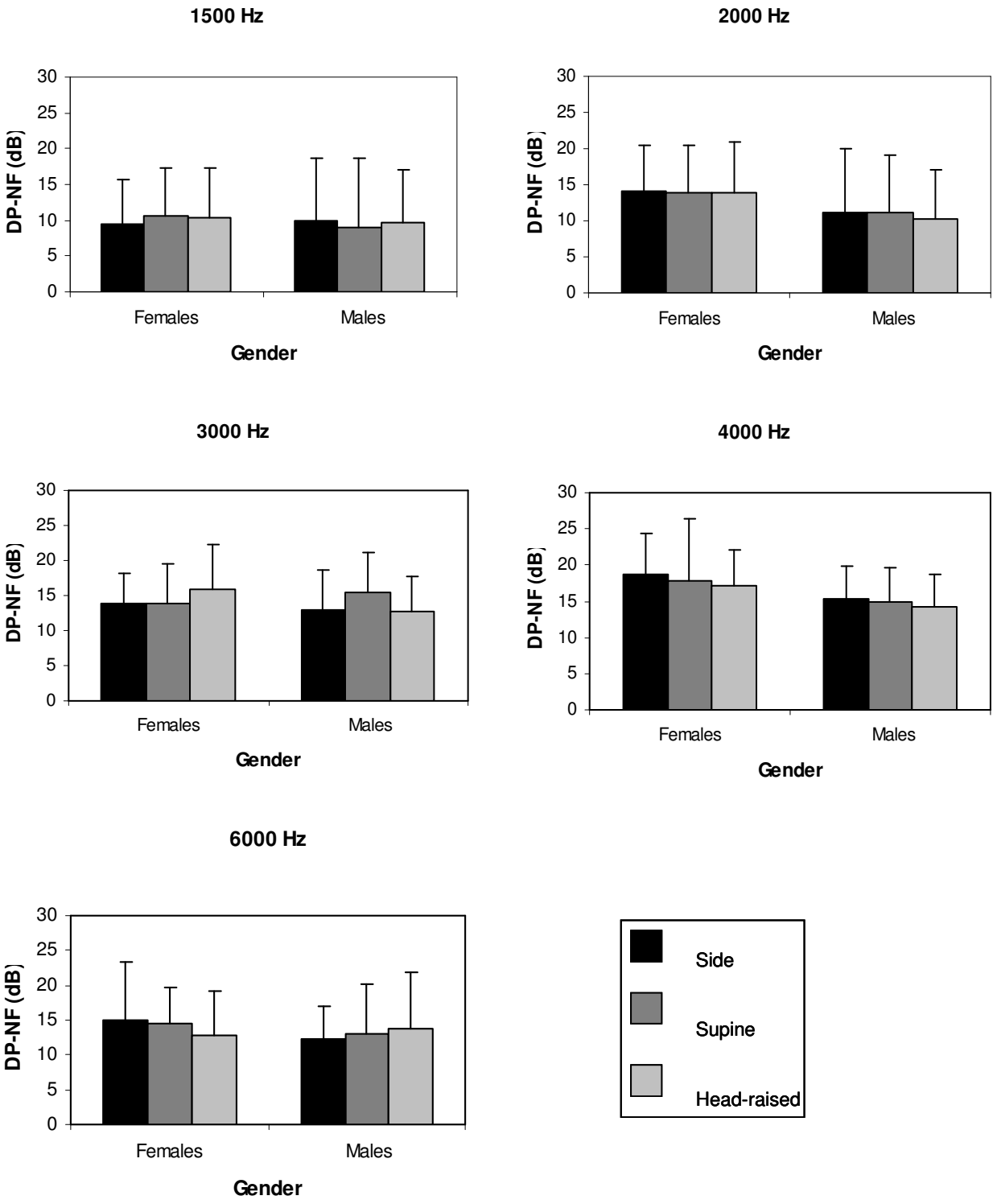

Figure 7. Mean DPOAE/noise (DP – NF), for females and males in three body positions. The error bars represent one standard deviation from the mean.

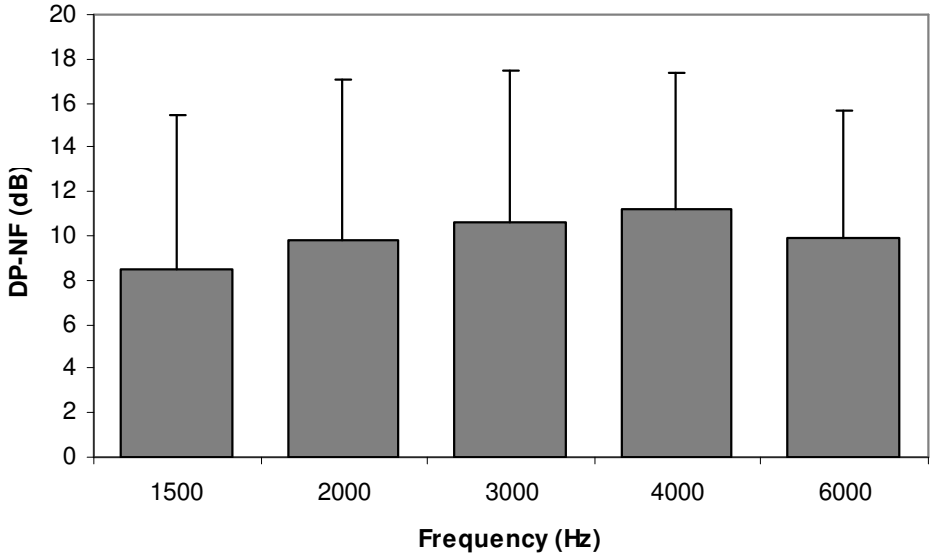

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Figure 8. Mean DPOAE/noise (DP – NF) for the five test frequencies collapsed across gender and body position. Error bars represent one standard deviation from the mean.

significant. Of the ten paired differences, all were significant except 6000 Hz and 4000 Hz, 6000 Hz and 3000 Hz, and 6000 Hz and 2000 Hz. Results of the post-hoc analyses are summarized in Table 4.

Test Time

Figure 9 shows the mean test time per body position for males and females. The error bars represent one standard deviation from the mean. The mean test time for each body position was approximately 30 to 52 seconds (*SDs* = 20 – 38 seconds). Body position does not appear to affect test-time. Mean data appear to indicate lower average test time for females than males in all body positions. The variability as indicated by standard deviations is larger in male participants for all body positions than female participants.

For the dependent variable of test time, a two way mixed model ANOVA was used with the between-subjects factors of gender and the within-subjects factor of body position. The main effect of body position was not significant, F (2, 88) = .495, p = .611. The main effect of gender was not significant, F (1, 44) = 4.001, p = .052. The interaction of body position and gender was not significant, F (2, 88) = .707, p = .496.

Referrals

Differences in pass rates across the three body positions were evaluated. There were a total of 94 tests obtained in each body position that could be evaluated

Table 4. Follow-up testing using paired sample t-tests to examine the main effect of frequency on DPOAE/noise (DP – NF).

Paired Frequencies (Hz)	***t***	***df***	***p***
6000 and 4000	-2.856	46	0.006
6000 and 3000	-0.404	46	0.688
6000 and 2000	1.709	46	0.094
6000 and 1500	4.521	46	*0.0001
4000 and 3000	2.55	46	*0.014
4000 and 2000	4.693	46	*0.0001
4000 and 1500	7.457	46	*0.0001
3000 and 2000	3.047	46	*0.004
3000 and 1500	6.464	46	*0.0001
2000 and 1500	4.482	46	*0.0001

Note. The alpha level of .05 was corrected using the Bonferroni adjustment by dividing the number of comparisons that were performed in the paired sample t-test, which resulted in $*p < .005$.

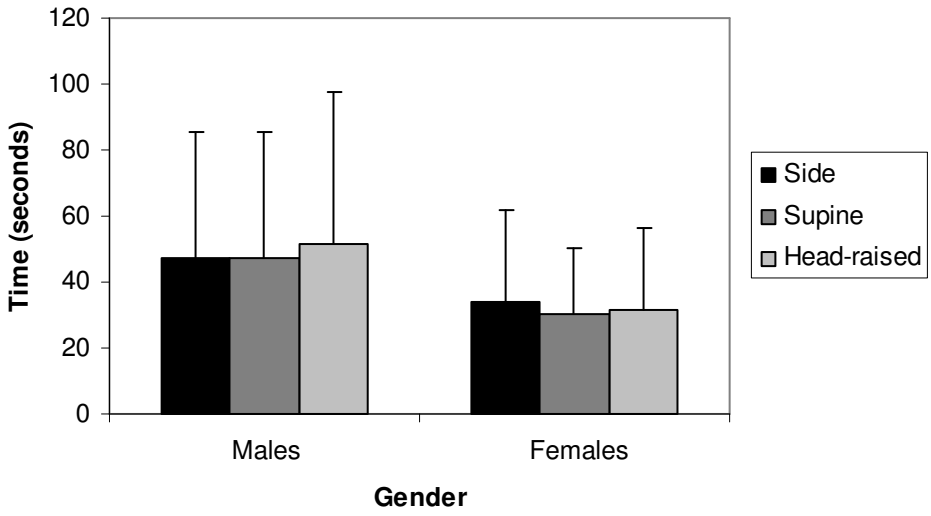

Figure 9. The mean test time for each of the three body positions for males and females. The error bars represent one standard deviation from the mean.

(47 participants x 2 test runs in each body position per participant). In order for a screening trial to be considered a pass, the DPOAE/noise needed to be equal to or greater than 6 dB at three of the five test frequencies. Although the participants of this study passed a hearing screening prior to participation, a small number of test runs collected for the current study did not meet the passing criteria. The number and percentage of "fails" for males and females and for the total sample in each body position are listed in Table 5. Nine participants were referred on one or more test runs and two out of the nine participants would have been referred on all six test runs. Table 6 lists the number of individuals who failed on one or more test runs for males and females and for the entire sample in each body position. Body position did not appear to impact the referral rate when viewed either as a function of the number of failed test runs (Table 5) or as a function of the number of individuals with one or more failed test runs (Table 6). Pearson Chi-Square revealed no significant main effect of body position on the referral rate, $p = .969$.

In all three body positions there were more referrals for male participants than female participants, although the numbers for both groups are small. Pearson Chi-Square revealed no significant main effect of gender on the referral rate, $p= .098$. Of the tests that did not meet passing criteria, the majority failed to meet the criteria at one additional test frequency. There was no consistent order effect observed for when (earlier or later) in the six test runs a referral occurred. There were also no consistent differences seen in referral rate related to birth method. Of the nine participants who referred on at least one test run, six were delivered vaginally (6/33 = 18 percent of those participants delivered vaginally) and three were delivered through

Table 5. Number and percentage of test runs that did not meet passing criteria ("fails") in each body position.

	One-Sided		Supine		Head-raised	
	Number	Percentage	Number	Percentage	Number	Percentage
Females	4	8.0	6	12.0	5	10.0
Males	8	18.1	7	15.9	7	15.9
Total Sample	12	12.8	13	13.8	12	12.8

Note: Ninety-four test runs were completed in each body position.

Table 6. Number and percentage of individual neonates with one or more test runs that did not meet passing criteria ("fails") in each body position.

	One-Sided		Supine		Head-raised	
	Number	Percentage	Number	Percentage	Number	Percentage
Females	2	8.0	3	12.0	2	8.0
Males	4	18.2	5	22.7	5	22.7
Total Sample	6	12.8	8	17.0	7	14.9

cesearean section (3/14 = 21 percent of those participants delivered through cesearean section). The mean age of the participants who referred on one or more test runs was 35 hours since birth (SD =11.62 hours). The mean age of the participants who passed all six of the tests was 33 hours since birth (SD =11.84 hours).

Chapter 6: Discussion

The goal of this study was to compare the effects of body position on DPOAE screening results from neonates in a hospital nursery. In the present study, infants were tested in the one-sided, supine, and head-raised positions, three positions that infants are commonly placed in during universal newborn hearing screenings. DPOAE levels, noise floor levels, DPOAE/noise, test time, and pass/fail rate were compared across positions to determine if body position should be considered during newborn DPOAE hearing screenings.

Test-Retest Variability

As mentioned previously, testing was conducted two times in each of the three body positions for the right ear of each neonate. The OAE probe was removed and reinserted before each measurement. In the current study, the mean difference in DPOAE level between the two measurements ranged from 2.0 dB to 4.8 dB. These values are consistent with variations in DPOAE level with changes in probe fit reported in other studies (e.g., Beattie et al., 2003; Wagner et al., 2008; Zhao & Stephens, 1999). Of note, the majority of studies reporting on test-retest reliability of DPOAEs utilized adult participants (e.g. Beattie et al., 2003; Wagner et al., 2008; Zhao & Stephens, 1999), and the measurements were made in a quiet room or sound proof booth. Lasky et al. (1992) reported on test-retest variability in neonates but did not provide specific ranges of differences for comparison with those obtained in the present study. However, Lasky et al. (1992) did note greater test-retest variability in their sample of neonates compared to their sample of adults. Testing for the current study was completed on neonates in a hospital nursery with moderate environmental

noise levels (mean = 60 dB SPL), which one might assume would lead to greater variability compared to adults. However, this was not the case.

The smaller than expected variability could be due to several factors. The nursery used for testing in the current study may be quieter than the hospital nursery used in Lasky et al. (1992), because the infants at Washington Hospital Center are primarily kept in their mother's hospital rooms during all hours (and not in the nursery). In addition, the same person did all of the testing during the current study. Therefore, factors that rely on tester judgment and experience, such as the choice of probe tip size, determination of an appropriate fit, and probe insertion technique were likely fairly constant across participants. Because an adequate probe fit may be more difficult to achieve in neonates, tester judgment and experience are likely to be particularly important. It is possible that more than one person collected the data for the previous study and that differences in tester technique contributed to greater variability in the neonate sample in that study.

In the current study, slight decreases in test-retest variability were noted with an increase in f2 frequency. The smallest variability of the five test frequencies was observed at 4000 Hz, and the variability at 4000 Hz was significantly smaller than the variability observed at 1500 and 2000 Hz. Other studies have reported an increase in test-retest variability with a decrease in f2 frequency (e.g. Roede et al., 1993; Wagner et al., 2008).

The mean difference in noise floor level between the two measurements in the current study was 2.7 dB to 6.4 dB. The variability in noise floor was similar for all test frequencies and not greater for the lower test frequencies (i.e. < 2000 Hz). No

comparable data for intra-participant noise floor variability is available for infants or adults to the best of our knowledge.

DPOAE Measurements and Body Position

The mean DPOAE levels in the current study ranged from approximately 12 dB SPL at 1500 Hz decreasing to approximately 0 dB SPL at 6000 Hz. DPOAE levels in the present study are fairly consistent with those of previous studies in this population that used similar stimulus parameters (e.g., Abdala, Oba, & Ramanathan, 2008; Lasky et al., 1992; Smurzynski et al., 1993). The mean DPOAE levels obtained in the current study are within 5 dB of the values indicated by Abdala et al. (2008) for term infants for all five test frequencies with the exception of 6000 Hz. The data reported by Abdala et al. (2008) indicated a significantly higher mean DP level (13 dB SPL) value than was obtained in the current study (0 dB SPL) at 6000 Hz. This difference could be due to differences in stimulus levels achieved with screening equipment compared to those measured in the custom system utilized by Abdala et al. (2008).

The mean DPOAE/noise levels in the present study averaged approximately 10 dB at 1500 Hz increasing to approximately 16 dB at 4000 Hz, the frequency with the greatest observed DPOAE/noise level. The findings of the current study are in agreement with those of Lasky and colleagues (1992) in their study of neonates. Lasky et al. (1992) report DPOAE/noise levels of approximately 10 dB at 1500 Hz increasing to approximately 18 dB at 6000 Hz.

Previous literature has suggested that a difference in intracranial pressure in different body positions may influence the DPOAE and noise floor levels obtained

during OAE testing (e.g., Antonelli & Grandori, 1986; de Kleine et al., 2001; Driscoll et al., 2004; Phillips & Farrell, 1992; Voss et al., 2006). In the present study, no significant differences in DPOAE level were found for the three body positions tested (one-sided, supine, and head-raised). The hypothesis that larger DPOAE levels would be observed in the one-sided body position was not supported. Additionally, no significant differences in noise floor levels were found between the three body positions in neonates in the current study. The hypothesis that noise floor levels would be greatest in the one-sided body position compared to the other two body positions was not supported. The hypothesis that noise floor levels would be lower in the supine body position compared to the other two positions was not supported. DPOAE/noise levels were also not significantly different across body positions.

The findings in the current study are not consistent with those of Driscoll et al. (2004), who reported differences in DPOAE levels of adult participants across the same three body positions. Driscoll and colleagues (2004) also reported a difference in the noise floor level measured during DPOAE testing in the supine, one-sided, and head-raised body positions. It is possible that no difference between body positions was noted in the present study because of differences between neonates and adults in the way body position affects intracranial pressure. A newborn infant's skull bones are not fused like an adult's; perhaps this has an impact on how intracranial pressure changes with changes in body position. The literature on differences in audiometric measures and the effects of body position has all been obtained in adult participants to date. Another possibility is that the significant effects seen in the study by Driscoll and colleagues (2004) were the result of order effects and not a true measurement of

differences in body position. The order of body positions was not randomized in the study of adult participants conducted by Driscoll and colleagues (2004).

In most previous studies, such as the study by Voss et al. (2006), the significant changes in DPOAEs were evident for test frequencies below 1500-2000 Hz. The stimuli in the current study included both 1500 Hz and 2000 Hz but it did not include lower frequencies. It is possible that changes in DPOAEs with body position at frequencies below 1500 Hz might be present in neonates, but these frequencies were not evaluated. Frequencies below 1000-1500 Hz are rarely included in clinical OAE protocols, because low frequency OAEs are more vulnerable to ambient noise and body noise than are higher frequency OAEs (Gorga et al., 1993). Therefore, potential changes at these lower frequencies are not as clinically relevant. It is also possible that, were these frequencies tested, changes at the lower frequencies in different body positions could be underestimated because of the overall larger noise floor level during testing for newborn hearing screenings.

With the exception of Driscoll et al. (2004) other literature on the effect of body position on audiometric measures has utilized a larger number and range of body positions than the current study (e.g., Antonelli & Grandori, 1986; de Kleine, et al., 2001; Phillips & Farrell, 1992; Voss et al., 2006). Differences in SOAEs, TEOAEs, and DPOAEs have been observed with changes in body position between the upright position and body positions in which the head was lowered below supine (de Kleine et al., 2000; de Kleine et al., 2001; Voss et al., 2006). The positions of one-sided, supine, and head-raised were chosen for the current study, because they are clinically relevant for DPOAE testing in neonates. It is possible that if additional

body positions were included, particularly positions in which the head were lowered below supine, greater physiologic differences would result and manifest in differences in OAE screening measurements in this population. However, testing additional body positions (i.e. prone, inverted, head lowered below supine) would not yield clinically relevant results even if a significant effect was observed. The three body positions tested in the current study were chosen because they are the most clinically relevant and feasible positions to test newborns in during hearing screenings.

Another difference between the current study and previous studies on the effect of body position on OAEs is that a screening protocol was utilized during this study. It is possible that differences for different body positions were not apparent utilizing stopping criteria and with the presence of extrinsic test factors (e. g., ambient noise, body noise) present during neonatal hearing screenings that are not present during well-controlled laboratory studies. Stopping criterion is utilized in the majority of OAE screening equipment. Thus, it is clinically relevant to be included in a study of this population. It is reassuring that DPOAE levels for those f2 frequencies and body positions used in a typical screening protocol are not influenced by body position.

Gender Differences

It was hypothesized that females would have larger emissions for all body positions when compared with those of the male participants. Mean data seemed to indicate larger DPOAE levels and DPOAE/noise levels in female participants when compared to male participants in all three of the body positions tested; however, these

differences failed to reach statistical significance. The failure to reach statistical significance is likely due to the large variability between measurements made in different participants evidenced by a large standard deviation in the current study for all measurements.

Literature on the gender differences in OAE measurements is conflicting; gender differences have been reported more consistently for TEOAEs as opposed to DPOAEs (Cacace et al., 1996; Gaskill & Brown, 1990; Moulin, Collet, Veuillet, & Morgan, 1993). Most studies that evaluated gender differences in DPOAEs have found that females exhibit slighter larger OAE levels that males (Cacace et al., 1996; Gaskill & Brown, 1990) although this finding is not expected to be clinically significant. Morleta et al. (1996) demonstrated small differences in OAEs between males and females in neonates, indicating larger measurable OAEs in females, but this finding failed to reach statistical significance, similar to the results of the current study.

Frequency Effects

For all three DPOAE measurements (DPOAE level, DPOAE/noise, and noise floor level) a significant effect of frequency was observed. This finding was also observed in a study of body position differences in adult participants (Driscoll et al., 2004) and in a large-scale study of DPOAE in neonates (Gorga et al., 2000). The frequency differences in DPOAE measurements are well documented in the OAE literature. Frequency effects noted in the present study are similar to those reported in the literature (e.g., Gaskill & Brown, 1990; Gorga et al., 1997; Gorga et al., 2000; Lasky et al., 1992).

A study on DPOAEs in infants by Gorga et al. (2000) indicated similar frequency effects to those found in the current study. These authors reported a decrease in DPOAE/noise with decreasing f2 frequency from 1000 Hz to 4000 Hz. The DPOAE/noise level also decreased for each f2 frequency below 4000 Hz in the current study. Gorga et al. (2000) also report that the measured DPOAE level was larger at 1500 Hz and 2000 Hz than 3000 Hz and 4000 Hz. The results of the current study also support an increase in mean DPOAE level with a decrease in f2 frequency with the smallest mean emission levels measured at 6000 Hz and the largest mean emissions measured at 1500 Hz. Current results also indicated an increase in mean noise floor level with a decrease in f2 frequency; this has been reported repeatedly in the literature (e.g., Gaskill & Brown, 1990; Gorga et al., 1997; Gorga et al., 2000; Lasky et al., 1992). As expected the largest mean noise floor level was recorded at 1500 Hz and the smallest mean noise floor was present at 6000 Hz.

Test Time

No significant difference was observed in the time it took to complete the hearing screening between the three body positions evaluated. It was expected that with the anticipated increase in DPOAE level in the one-sided body position the stopping criteria of the screening would be reached first in this position; however, this was not supported by the current study. The mean test time for each body position was within two seconds of the other body positions tested.

The average test time across body positions was approximately 40 seconds. Only one ear was tested in the current study. If the time in the current study is doubled, the test time is reasonably similar to the average time of two minutes

reported by Norton et al. (2000b) for a DPOAE hearing screening of both ears. This supports the use of DPOAE screenings as an efficient means of screening for congenital hearing impairment regardless of the infant's body position.

Screening Outcomes

A small number of newborns in the present sample passed the initial hearing screening but would have been referred on the majority, if not all, of the follow-up testing for the study. It is possible that with multiple probe insertions, debris that was present in the ear canal was pushed further towards the tympanic membrane for some test trials. The movement of the debris in the external auditory canal may have occluded the canal or limited the movement of the tympanic membrane resulting in a referral on re-screening tests conducted for participation in the current study (Eavey, 1993; Tsui, McPherson, Wong, & Ng, 2008). Furthermore, ear canal collapse is more common in infants due to cartilaginous ear canals and may have contributed to some of the failed test runs. There were no obvious order effects as to which of the six tests the participants failed. In general, the trials that failed to meet the pass criteria for screening during the follow-up testing for this study indicated low DPOAE level measurements and not significantly high noise floor levels. For practical considerations when conducting hearing screenings, it is reassuring that differences are not evident in the pass/fail rate of the three body positions tested. The referral rate reported in the current study is consistent with that reported by other studies (e.g., Gorga et al., 2000; Norton et al., 2000b).

Limitations

The current study had 47 participants which is a significantly larger number than many of the other studies that looked at the effect of body position on audiometric measures (e.g., Antonelli & Grandori, 1986; de Kleine, et al., 2001; Phillips & Farrell, 1992; Voss et al., 2006). However, it is possible that in the infant population differences in body position may have been evident with a larger number of participants. As mentioned previously, the use of stopping criteria and the limited range of body positions used in the current study may have underestimated differences in body position in the infant population. Although, this may have influenced the outcomes of the current study, the study was designed to indicate if differences in body position influence measurements during routine newborn hearing screenings, therefore, common newborn hearing screening protocol and technique were replicated.

Future Directions

Future research is indicated to determine the effect of body position on DPOAEs, including a well executed study of adult participants. The most compelling literature to indicate that DPOAEs are influenced by body position is that of Driscoll and colleagues (2004). The significant effects observed in the Driscoll study may have been the result of order effects and not a true measure of differences in different body positions. A study where order of body position is randomized would give a better indication of the true effects of body position on DPOAEs. Preferably body positions that are clinically feasible would be examined.

Future research on the effects of body position on universal newborn hearing screening outcomes could be used to evaluate whether a difference in measurements is observed with TEOAE hearing screenings. Body position has been shown to effect TEOAE measurements in adults (e.g., de Kleine et al., 2001; Phillips and Farrell, 1992). It would be relevant to determine if these effects are also observed in infants and for body positions that are utilized during newborn hearing screening programs (e. g., head-raised, supine, one-sided).

Summary and Conclusions

No significant differences in DPOAE levels, noise levels, and DPOAE/noise levels obtained in the three body positions were observed during newborn hearing screenings. Test time and failure rates also were not significantly different across the three body positions. The failure to find significant differences in the DPOAE measurements obtained in different body positions during newborn hearing screenings is, from a clinical perspective, a positive one in that it is not necessary to consider body position during protocol design. The most convenient position to test an infant is one in which they are quiet. Results of the present study suggest that infants from the well-baby nursery do not need to be moved to a specific body position in order to improve screening outcomes or reduce the test time required to complete a hearing screening.

IRB number: 2007-286	**Clinical Site IC Version:** 10/29/07
Project Title: The Effect of Body Position on Distortion Product Otoacoustic Emissions in Neonates	
Principal Investigator: Krista Heinlen	**Institution:** Washington Hospital Center

MedStar Research Institute Informed Consent for Clinical Research

INTRODUCTION

We are inviting your baby to participate in this research study called "The Effect of Body Position on Distortion Product Otoacoustic Emissions Testing in Neonates." Your baby was selected as a possible participant in this study because he/she has passed the hospital hearing screening and he/she does not have any known risk factors for hearing loss.

Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this research is to study how testing your baby when they are lying on one side, on their back, or with their crib raised affects the measurements made during hearing screenings.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you or your baby normally have;
- You and your baby may or may not benefit from taking part in the study, but knowledge may be gained from your baby's participation that may help others; and
- Your baby may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your baby's participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?

The investigator is Krista Heinlen an employee of the Hearing and Speech Department and Teri Wilson-Bridges the Director of the Hearing and Speech Department.

WHO CANNOT PARTICIPATE IN THIS STUDY?

Your baby cannot be in this study if any of the following apply:

- They have not passed the initial hospital newborn hearing screening.
- They have any risk factors for hearing loss.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About **50** people will take part in this study, worldwide. **50** people will be recruited at this site.

WHAT HAPPENS IF I AGREE TO HAVE MY BABY BE IN THE STUDY?

If you agree for your baby to be in this study, they will have the following tests and procedures:

The test used in this study is Distortion Product Otoacoustic Emissions testing. This is the same test that your baby passed during their hearing screening. A small plug will be placed in the outer part of your baby's ear. Your baby will hear two moderate level tones coming from the plug, a microphone in the plug will measure the response from your baby's ear. The test will be repeated three times; while your baby is lying on their side, with their crib raised, and with them lying on their back. Your baby can sleep or rest quietly throughout the test.

HOW LONG WILL MY BABY BE IN THE STUDY?

Testing will be done in one session and it will take approximately 15 minutes to complete.

The investigator may decide to take your baby off this study if it is believed to be in your baby's best interest, your baby fails to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator believes are important.

You can stop your baby from participating at any time.

If you suddenly withdraw your baby from the study, we will not be able to use any of the information gathered from their participation. There are no consequences associated with removing your baby from the study.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

There are no anticipated risks associated with your baby's participation in this research study. The test used in this study is used routinely during infant hearing screenings. The sounds played to your infant's ear are at moderate levels and are not dangerous to hearing. Standard precautions for prevention of the spread of infection will be utilized including using a new probe tip for each baby tested.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study is not designed to provide direct benefits to any participants. You or your baby will not receive any direct benefit from participation in this experiment. This experiment is not designed to help you or your baby personally, but to help the experimenters learn more about factors that might affect hearing screenings in newborns. We hope that, in the future, other people may benefit from this study by learning about factors that influence the outcome of hearing screenings for babies.

WHAT OTHER OPTIONS ARE THERE?

Instead of having your baby participate in this study, you have these options:

- You always have the option for your baby to not be in this study or to refuse any medical treatment.

WHAT ABOUT CONFIDENTIALITY?

You and your baby's personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including your baby's personal health information and the information discovered during this study. If you do not wish to sign this permission form your baby will not be allowed to participate in this study.

WILL I BE PAID FOR HAVING MY BABY PARTICIPATE IN THIS STUDY?

You will not be paid for having your baby participate in this study.

WHAT ARE THE COSTS?

You do not have to pay anything for your baby to be in this study.

WHAT IF MY BABY BECOMES INJURED OR ILL DURING THE STUDY?

We will make every effort to prevent injuries and illness from being in the study. In the case of an injury, illnesses, or other harm occurring during, or resulting from, the study, emergency medical treatment is available but will be given at the usual charge by Washington Hospital Center. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.

If you have an injury or illnesses occurring during, or resulting from the study, you, your medical insurance, a third-party payer, or a government program you've enrolled will be expected to provide coverage for your medical care. Krista Heinlen does not intend to provide reimbursement for costs of medical treatment for injury or illness if such costs are not covered by your medical insurance, a third-party, or governmental programs providing such coverage.

No funds have been set aside, by the Washington Hospital Center, the MedStar Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of the exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to have your baby be in the study without anyone misleading or deceiving you; and

IRB number: 2007-286	**Clinical Site IC Version:** 10/29/07
Project Title: The Effect of Body Position on Distortion Product Otoacoustic Emissions in Neonates	
Principal Investigator: Krista Heinlen	**Institution:** Washington Hospital Center

- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights your baby may have as a research participant. You may choose not to have your baby take part in or leave the study at any time. If you choose to not have your baby take part in or to leave the study, you and your baby's regular care will not be affected and you and your baby will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Krista Heinlen, at (202) 877-6717. If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the MedStar Research Institute. Direct your questions to the Office of Regulatory Affairs at:

Address:	MedStar Research Institute	Telephone:	(301) 560-7339
	6495 New Hampshire Avenue	Toll Free:	(800) 793-7175
	Suite 201	Fax	(301) 560-7336
	Hyattsville, MD 20783		

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

Signature of Person Obtaining Consent _____ Date of Signature _____

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to have my baby be in this study. I am free to stop having my baby in the study at any time without need to justify my decision and if I stop him/her from being in the study I understand it will not in any way affect my or my baby's future treatment or medical management. I agree to cooperate with Krista Heinlen and the research staff and to tell them immediately if my baby experiences any unexpected or unusual symptoms.

Participant's Signature _____ Date of Signature _____

Signature of Witness _____ Date of Signature _____

Signature of Legally Authorized Representative (When Appropriate) _____ Date of Signature _____

Relationship to Participant (When Appropriate) _____ Date of Signature _____

RESEARCH AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Who may have and use my health information?

I agree to allow **Krista Heinlen** and their staff (together called "Researchers"), to receive, use, have and disclose my personal health information (as permitted below) for the reason(s) described in the Informed Consent Form used for this study (identified above) and as needed to conduct the research.

- Laboratories and other individuals and organizations that look at my health information in connection with this study;
- Members and staff of the Institutional Review Board(s), Ethics Committee(s), Data Safety Monitoring Boards (DSMB) and all other review boards or persons who watch over how the research is performed and/or monitor the safety and success of the research, including the Institution that approves this study;
- The Patient Advocate or Research Ombudsman (people who watch out for my best interest);
- The United States Food and Drug Administration (FDA), any other Federal or State Agencies that watch over the safety of the study and how the study is managed or run, and/or governmental agencies in other countries which fill similar oversight roles;

Who may give (release or disclose) my health information?

I wish to allow **Washington Hospital Center**, all my doctors and my other health care providers, and others who generate or use my health information, to give my health information in my medical or other records to the Researchers, Sponsor(s) and others listed above, for the research purposes described in the Informed Consent Form used in this study and as otherwise described below.

What health information may be used for this research study? (Check all that apply)

☐ All my personal information in my medical records or other health care related records requested by the Researchers to be able to do the research described in the Informed Consent Form for this study;
☐ All my personal information made or collected during the research described in the Informed Consent Form for this study; *and/or*
☐ Only the following information: _____

***Note:** if any of the above records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse, sexually transmitted disease, or includes records or information from another healthcare provider, I agree that I am hereby authorizing the release and use of this information.*

What could happen if I agree to this use or disclosure of my health information?

- There is the possibility that Federal privacy laws (laws that protect the privacy to my personal health information) may no longer protect it from being given to another person, class of persons, and/or company.
- Once information that could be used to identify me has been removed and my information is no longer identifiable (connected to my identity), the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Researchers and Sponsor to others, including for other research reasons.
- The Researchers and Sponsor have agreed that no publication or presentation of the research will reveal my identity without my separate specific written permission and authorization (agreement) (even if I revoke (take back) this Authorization (agreement)).

What rights do I have?

- While my health care and benefits relating to healthcare outside the study will not be affected if I do not sign this form, I understand I have the right to refuse to sign this Authorization (agreement), but that I will not be able to participate in the research referred to in this form.
- I may change my mind and cancel this agreement at any time. To cancel this agreement, I must write to: Krista Heinlen Washington Hospital Center, 110 Irving St. NW, Room GA102, Washington, DC 20010. However, if I cancel this agreement, I may no longer be allowed to participate in the research and may no longer receive research-related treatment. Also, even if I cancel this agreement, the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.
- I will be given a copy of this agreement after I have signed it.

When does this Authorization expire?

This Authorization has no expiration date, but shall expire at the end of the research study identified above.

By signing below I represent and warrant that I have authority to sign this document and authorize the use or disclosure of PHI and that there are no restrictions that would prevent me from authorizing the use or disclosure of this PHI.

_____ Signature of Participant *(or Participant's Personal Representative)*

_____ Date

_____ Printed Name of Participant *(and if applicable print name of Participant's Personal Representative)*

_____ Representative's authority to sign for Participant, *(parent, guardian, power of attorney for healthcare, etc.)*

MedStar Research Institute

Georgetown University

MedStar Research Institute
APPROVAL DATE NOV 0 2 2007
APPROVAL EXPIRES N/A
IRB APPROVED

2.8.07 .v.7

Appendix B

Initials_____Date_____

CONSENT FORM

Title: The Effect of Body Position on Distortion Product Otoacoustic Emissions in Neonates

Why is this research being done?
This research is being conducted by Krista Heinlen and Dr. Tracy Fitzgerald in the Department of Hearing and Speech Sciences at the University of Maryland, College Park. We are inviting your baby to participate in this research project because he/she has passed the hospital hearing screening and he/she does not have any known risk factors for hearing loss. The purpose of this research is to study how testing your baby when they are lying on one side, on their back, or with their crib raised affects the measurements made during hearing screenings.

What will your baby need to do?
All testing will take place in the nursery at Washington Hospital Center, Washington, DC. The test used is the same test that your baby passed during their hearing screening. A small plug will be placed in the outer part of your baby's ear. Your baby will hear two moderate level tones coming from the plug, a microphone in the plug will measure the response from your baby's ear. The test will be repeated three times; while your baby is lying on their side, with their crib raised, and with them lying on their back. Your baby can sleep or rest quietly throughout the test.

What about confidentiality?
You and your baby's personal information will be protected to the maximum extent possible. To help protect confidentiality, all data will be coded using a number. All data and consent forms will be kept in a locked file cabinet at the University of Maryland, College Park. If we write a report or an article about this project, your baby's data will be presented by the code number and no identifying information will be used. The information obtained in this study may be shared with representatives of the University of Maryland, College Park or governmental authorities if we are required to do so by law.

What are the risks of this research?
There are no known risks associated with your baby's participation in this research study. The test used in this study is used routinely during infant hearing screenings. The sounds played to your infant's ear are at moderate levels and are not dangerous to hearing. Standard precautions for prevention of the spread of infection will be utilized including using a new probe tip for each baby tested.

What are the benefits of this research?
You or your baby will not receive any direct benefit from participation in this experiment. This experiment is not designed to help you or your baby personally, but to help the experimenters learn more about factors that might affect hearing screenings in newborns. We hope that, in the future, other people may benefit from this study by learning about factors that influence the outcome of hearing screenings for babies.

Initials_____Date_____

Does my baby have to be in this research?
Your baby's participation in this research is completely voluntary. You may choose to not have him/her take part at all. If you do not give consent for your baby to participate you and your baby will not be penalized or lose any benefits to which you otherwise qualify.

What if I have questions?
This research is being conducted by Krista Heinlen and Dr. Tracy Fitzgerald, in the Department of Hearing and Speech Sciences at the University of Maryland College Park. If you have any questions about the research study itself, please contact:

Tracy Fitzgerald, Primary Investigator
Lefrak Hall Room 0100
College Park, MD 20742
tfitzgerald@hesp.umd.edu
(301)405-7776

If you have questions about your rights as a research subject or wish to report a research-related injury, please contact:

Institutional Review Board Office
University of Maryland
College Park, Maryland 20742
irb@deans.umd.edu
(301)405-4212

This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.

Statement of Age of Subject and Consent:
Your Signature indicates that:

- The research has been explained to you.
- Your questions have been fully answered.
- You freely and voluntarily choose to have your baby participate in this research project.
- You are over 18 years of age and the parent or legal guardian of the infant named below.

NAME OF INFANT PARTICIPANT _____
(please print)

PARENT SIGNATURE_____**DATE**_____

PARENT NAME (please print)_____

IRB APPROVED
VALID UNTIL
SEP 27 2008
UNIVERSITY OF MARYLAND
COLLEGE PARK

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