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Tympanometry in children with Down syndrome

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TYMPANOMETRY IN CHILDREN WITH DOWN SYNDROME

by

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requirements for the degree of:

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Abstract: The primary aim was to determine whether or not the current standard tympanogram used in those older than 6 months, i.e. the 226 Hz probe tone, is an accurate measure of middle ear effusion in children with Down syndrome. This study also attempted to determine whether or not the 1000 Hz tympanometric probe tone may be a better measurement of middle ear status for this population.

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Introduction

Tympanometry is a commonly used part of the audiologic test battery to evaluate middle ear function. This is a particularly important measure in infants and children because it is not always possible to obtain valid bone conduction measures to assess an air-bone gap in instances of possible conductive hearing loss. The current standard for clinical practice is the use of a 226 Hz probe tone for all children and adults above 6 months of age (ASHA, 2004; Katz, 2002; Nozza, Bluestone, Kardatzke & Bachman, 1994). Tympanometry with a 226 Hz probe tone in children younger than six months has been proven to show inconsistent relationships with otoscopic examinations (Smith et. al., 2006). With the population younger than six months of age, a 1000 Hz probe tone is used as standard practice and has been shown to produce valid results (Alaerts, Luts & Wouters, 2007; Baldwin, 2006; Meyer, Jardine & Deverson, 1997; Paradise, Smith & Bluestone, 1976).

There are some populations that may need special consideration in choosing the most appropriate probe tone. Because tympanometry is such an integral component of the audiologic battery, it is important that the parameters that provide the most accurate measurement be used clinically with all populations. Characteristics of the ears of children with Down syndrome are similar to that of neonates, such as the small size of the ear canals in both populations. The established sensitivity of 1000 Hz tympanometry in neonates and the similar ear characteristics lead us to believe that the 1000 Hz probe tone may be a more accurate measure of middle ear function in the Down syndrome population. Clinical experience has also shown many false positives using the 226 Hz probe tone with the Down syndrome population, indicating limited static admittance when middle ear effusion actually does not exist.

Lewis, Bell & Evans (2011) completed a pilot study investigating the use of the 1000 Hz probe tone versus the 226 Hz probe tone in the Down syndrome population. There were 26 subject ears included in this study with ages ranging from 1 to 11 years. The results of this study indicated sensitivity of both measures as 100%. However, specificity of 100% was indicated with the 1000 Hz probe tone compared to 71% specificity with the use of the 226 Hz probe tone. The results of this study give us reason to believe that 1000 Hz may in fact be a more accurate tympanometric measurement (Lewis, Bell & Evans, 2011).

Physiologic issues have been found to be the cause of the lack of validity in using the 226 Hz probe tone in young infants. These issues include the lack of fusion of the tympanic membrane to the tympanic ring, the overall decrease in the mass of the middle ear system, and the formation of the bony ear canal wall (Lantz, Petrak & Prigge, 2004). Because of these physiologic differences, the middle ear system is primarily mass dominated. This means that the input admittance of the neonatal ear is dominated by the mass elements of the middle ear, such as the ossicles. In contrast, the middle ear system in adults is stiffness-dominated. Therefore, the input admittance of the adult ear is dominated by the resistive components of the middle ear, such as the reactive force exerted by the cochlear fluids. The shift from mass dominance to stiffness dominance occurs due to maturation of the middle ear, causing tightening of the ossicular joints as well as the gradual loss of ossicular mesenchyme (Meyer, Jardine & Deverson, 1997). Maturation of the external ear and middle ear system generally begins at around four months of age, reaching adult size by six months of age (Son, Park, Kim, Hong, Lim, Choi & Lee, 2012).

The neonatal mass dominated middle ear system has a lower resonant frequency than the stiffness dominated middle ear system of adults, as opposed to the higher resonant frequency of

the adult middle ear (Holte, Margolis & Cavanaugh, 1991). The 226 Hz probe tone is the accepted test frequency for the adult population due to the easily identifiable, reproducible peak formation at this frequency (Liden, Peterson & Bjorkman, 1970). The 1000 Hz probe tone has been accepted for neonates and has sensitivity of 99% and specificity of 89% in identifying middle ear dysfunction (Baldwin, 2006). Other frequency probe tones have also been investigated in the neonatal population. One study revealed a strong correlation between the use of the 1,000 Hz tone and the 678 Hz tone, indicating that the use of more than one would be considered redundant in the clinical setting (Harris, Hutchinson & Moravec, 2005). In contrast Baldwin (2006) reported that the 678 Hz probe tone yielded a higher number of unclassifiable tympanometric traces than the 1000 Hz probe tone in infants, making it a much less reliable measurement of middle ear function.

Although a number of high-frequency probe tones have been explored over the past 30 years (Baldwin, 2006; Kei et al., 2007; Margolis, Van Camp, Wilson & Creten, 1985), a 1000 Hz probe tone is the most commonly used frequency at this time (ASHA, 2004; Kei et al., 2003; Margolis et al., 2003). Guidelines for the use of tympanometry in clinical practice have been outlined by Alaerts et al. (2007). This guideline stated that the 1000 Hz probe tone should be the frequency of choice for infants less than three months of age. For those older than nine months of age, the 226 Hz probe tone should always be used (Alaerts, Luts & Wouters, 2007). Multifrequency tympanometry indicated that the shift in resonant frequency occurs at around six months of age in neonates (Alaerts, Luts & Wouters, 2007).

Limited normative data are available for 1000 Hz tympanometry. The current normative data is that compiled by Kei et al. (2003) and Margolis et al. (2003) in the neonatal population. These normative studies by Kei et al. (2003) and Margolis et al. (2003) include the following

measures:

- Y^{+200} mmho – Static admittance at +200 daPa

- Y^{-200} mmho – Static admittance at -200 daPa

- $Y^{-400\ (TAIL)}$ mmho – Static admittance at the admittance value measured at the tail, approximately -400 daPa

- Y^{PEAK} – Static admittance at the peak pressure

- Ypc^{+200} mmho – Peak compensated admittance, with compensation at +200 daPa

- Ypc^{-200} mmho – Peak compensated admittance, with compensation at -200 daPa

- $Ypc^{-400\ (TAIL)}$ mmho – Peak compensated admittance, with compensation at the admittance value measured at the tail, approximately -400 daPa

The instrumentation settings have an impact on the normative data. In particular pump speed, pressure change direction (positive to negative or negative to positive), and range of pressure change affects tympanometric measures. Margolis et al. (2003) used a positive to negative direction at a rate that varied from 600 daPa/sec at the tails to 200 daPa/sec near the peak. Kei et al. (2003) also used a positive-to-negative direction; however the sweep rate used was 400 daPa/sec. Swanepoel et al. (2007) completed a normative study in infants from birth to four weeks of age. However, this study only contained normative data for tympanometric peak pressure and peak admittance (Swanepoel et. al., 2007). Because there are significant differences among the data for the three normative studies, consensus is still lacking for a standardized approach to categorizing and interpreting of the 1000 Hz tympanogram.

Although normative data has been compiled on tympanometry in normal neonates and adults, there has been little to no data gathered about tympanometry in children and special populations such as Down syndrome. Down syndrome is one of the most common genetic

abnormalities affecting as many as one in 700 births (Raut, et. al., 2011). Multiple

malformations and cognitive impairment are associated with this syndrome. In particular,

children with Down syndrome have markedly small ear canals, auricles and tympanic

membranes and have a three times higher prevalence of chronic ear disease and secondary

hearing loss due to chronic ear disease than other children with developmental delays

(Committee on Genetics, 2001; Shott, 2006). Balkany et al. (1979) reported 78% of ears tested

in a population of 102 children with Down syndrome showed some degree of hearing loss

associated with recurrent otitis media. Cognitive impairment in children with Down syndrome

also leads to speech and language delays. Therefore, it is imperative to identify and treat any

hearing issues as soon as possible to provide these children with optimal access to speech and

language cues. It has been shown that with aggressive treatment and early intervention, the

prevalence of hearing loss in the pediatric Down syndrome can be reduced to as little as 2%

(Shott, Joseph & Heithaus, 2001).

The current standard for diagnosing otitis media is pneumatic otoscopy (Alper et al.,

2004). The accuracy of this procedure is affected by the anatomy of the ear, professional

performing the otoscopic examination, and the equipment used to visualize the tympanic

membrane. In cases in which tympanic membrane visualization is difficult, binocular

microscopy can be used. Rogers et al. (2010) showed the sensitivity of binocular microscopy to

be 88% and specificity to be 89% compared to pneumatic otoscopy with sensitivity of 67.9% and

specificity of 81.4% in a population of children aged 5 months to 5 years. Another study showed

84.6% sensitivity and 100% specificity of determining presence of middle ear fluid compared to

the gold standard of myringotomy in normal developing children aged 1 to 10 years (Harris,

Hutchinson & Moravec, 2005). The characteristically small ear canals in children with Down

syndrome make otoscopy and microscopy difficult. Therefore, tympanometry can play a large part in helping the physician make a diagnosis on the presence or absence of fluid when otoscopy is difficult.

Purpose

This primary aim of this study is to determine the accuracy of the 226 Hz tympanometric probe tone in children with Down syndrome. In doing so, we hope to determine a standard for evidence based practice that can be used clinically with the Down syndrome population to ensure them the best quality of care. The goals of the current study are as follows:

1) Compare the results of otoscopic evaluations and 226 Hz probe tone tympanometric measurements in children with Down syndrome in a retrospective review.

2) Collect normative data for 1000 Hz tympanometry for those older than six months.

3) Based on normative data collected in the study and in the literature, prospectively determine which tympanometric probe tone, 226 Hz or 1000 Hz, is a more accurate measure of determining middle ear status in children with Down syndrome.

Methods

Approval to perform this research on human subjects was received from the Washington University in St. Louis School of Medicine Human Research Protection Office prior to beginning this study. The current study includes a retrospective review, normative data collection, and prospective data collection. A waiver of written consent was obtained for the retrospective review. Informed consent was obtained from parents or participants prior to participation in the normative and prospective portions of the study.

Participants

Retrospective:

This portion was a retrospective cohort study using medical record review of children with Down syndrome who were seen by both the Department of Audiology and the Department of Otolaryngology at St. Louis Children's Hospital for appointments on the same day in the calendar years 2007 to November 2012. Medical records were only reviewed for patients who were between the ages of 6 months and 5 years. Participants were required to have had a 226 Hz tympanogram completed as well as an otologic evaluation to be included in this study.

A total of 151 medical charts were examined. Of these 151 charts, 60 participants had multiple appointments. Multiple appointments were included, resulting in 151 unique participants and 238 data entries.

Normative:

Participants were recruited from both St. Louis Children's Hospital Department of Audiology and the Department of Otolaryngology and also from the community. Those

recruited through St. Louis Children's Hospital and from the community were those with known normal middle ear function. The age range of participants in this portion of the study was 2.57 months to 29.59 years of age. This particular age range was chosen because it has been shown that tympanometric shapes vary little once middle ear maturation has occurred after about 6 months of age (Holte, Margolis & Cavanaugh, 1991). There were 6 male participants and 14 female participants. A total number of 40 ears were used for this portion of the study, with 20 right ears and 20 left ears.

Prospective:

Children with Down syndrome between the ages of 6 months and 5 years were recruited from the Department of Audiology and the Department of Otolaryngology at St. Louis Children's Hospital. Potential research participants were those children having both an audiologic exam and an otologic exam on the same day. Potential participants were identified through review of both the Department of Audiology and the Department of Otolaryngology's schedules and patient charts. Parents of patients who were potential participants were spoken to prior to their child's appointment and were required to sign written consent to allow their child to participate in the study. Children were excluded if they had patent pressure equalization (PE) tubes or excess fluid draining from the ears. Participants with PE tubes that were not functioning were included within the study.

A total number of 49 potential participants were recruited for this study. Out of those potential participants, 37 consented to participate. The total number of individual participants included within the study was 27, with a total number of 50 ears. Consented participants were excluded in the instances of patent PE tubes (9), active drainage (1), cerumen impaction (1) or

excessive movement during tympanometry (1). Of the 50 ears, there were 24 right ears and 26

left ears and a total of 13 male participants and 14 female participants.

Procedure

Retrospective

Medical records of the participants were examined and participant demographics,

including age and gender, were recorded. Additional information obtained included the

otolaryngologist or nurse practitioner that performed the otoscopic exam and also the audiologist

who performed the tympanogram. The type of otoscope used for examination was recorded as

either pneumatic otoscope, binocular microscope, both, or unknown. The results of the ear

examination were recorded as one of the following for each ear: air, fluid, air and fluid, or

indeterminate. Tympanometric measures for the 226 Hz probe tone included static admittance,

peak pressure and ear canal volume.

Normative

Because the participants had known normal middle ear function determined by patient or

parental report or a recent completed audiogram, a thorough otoscopic examination by an

otolaryngologist or nurse practitioner was not required. Participants had both a 226 Hz

tympanogram and a 1000 Hz tympanogram performed by either a licensed audiologist or an

audiology graduate student. A study by Karzon (1991) indicated that a statistically significant

change in static admittance is noted on the second tympanometric sweep in comparison to the

first sweep. Therefore, participants tested on even numbered days began with the 226 Hz probe

tone and those tested on odd numbered days began with the 1000 Hz probe tone to eliminate the

effect that being the secondary tympanogram might have on the data.

Values of Y^{+200}, Y^{-200}, $Y^{-400 \text{ (TAIL)}}$ and $Y^{\text{PEAK,}}$ were manually recorded from the 1000 Hz tympanogram. Peak compensated admittance values of Ypc^{+200}, Ypc^{-200} and $Ypc^{-400 \text{ (TAIL)}}$ were calculated following the test. Ypc^{+200} is calculated by subtracting the difference between Y^{PEAK} and Y^{+200}. Ypc^{-200} is calculated in the same fashion, subtracting Y^{-200} from Y^{PEAK}. The Ypc^{-400} $^{\text{(TAIL)}}$ is calculated by subtracting the static admittance at the farthest negative value recordable by the tympanometer from the Y^{PEAK}. Figure 1 shows an example of a peaked 1000 Hz tympanogram and the given measures recorded. Following Figure 1, Table 1 provides the actual static admittance measurements in mmhos for the example tympanogram.

Figure 1 – 1000 Hz Tympanogram Measurements

TYMP DIAGNOSTIC   TEST 1

Ya   1000Hz   L

mmho

Y^{-200}

$Y^{-400 \text{ (TAIL)}}$ Y^{PEAK} Y^{+200}

-400   -200   0   +200

← 600/200daPa/s   daPa

C1:   1.0

             daPa   mmho

TYMP 1:   -110   2.0
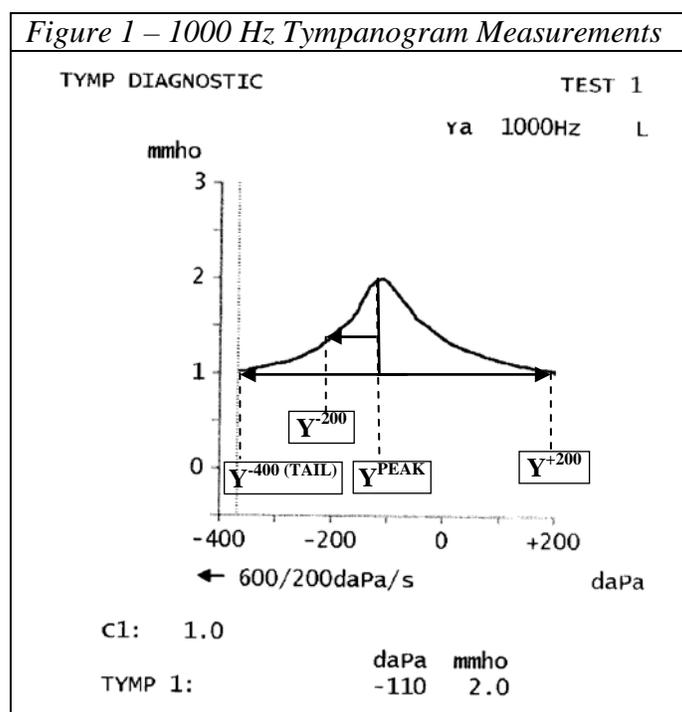
Table 1 – 1000 Hz Tympanogram Measurements							
	Y^{+200}	Y^{PEAK}	Y^{-200}	$Y^{-400 \text{ (TAIL)}}$	Ypc^{+200}	Ypc^{-200}	$Ypc^{-400 \text{ (TAIL)}}$
mmho Value	1.0	2.0	1.39	1.03	1.0	0.61	0.97

Prospective

In the same fashion as the normative portion of this study, the participants for prospective portion had both a 226 Hz and 1000 Hz tympanogram performed by a certified audiologist or audiology graduate student. The varying of which tympanogram was performed first, the 226 Hz or 1000 Hz, was done for the prospective portion in the same fashion as the normative portion, as indicated by Karzon (1991). Values of Y^{+200}, Y^{-200}, $Y^{-400 \text{ (TAIL)}}$ and $Y^{PEAK,}$ were manually recorded from the 1000 Hz tympanogram via cursor placement. Values of Ypc^{+200}, Ypc^{-200} and Ypc^{-400} were, once again, calculated by an audiology graduate student following the test.

Following the audiology appointment, participants were also scheduled to see an otolaryngologist or nurse practitioner for an ear examination. Without knowledge of the tympanometric results, the examiner determined the status of the middle ear as air, fluid, air and fluid, or indeterminate. A comment section was also available if additional information was gathered during examination.

Equipment

The GSI 38 Automatic Tympanometer was used for the 226 Hz tympanogram for all three parts of the study. Tympanometry was performed by presenting a 226 Hz probe tone at 85.5 dB SPL into the ear canal while air pressure changed from +200 daPa to -400 daPa. The rate of pressure change was 600 daPa/sec for tympanogram slopes of < 0.2 ml per 24 daPa and 200 daPa/sec for tympanogram slopes of > 0.2 ml per 24 daPa. Data from Holte, Margolis and Cavanaugh (1991) indicates that a tympanometric sweep in the + to – direction leads to the most reliable results and reduction of the chance for collapsed ear canals.

The GSI TympStar Version 2 was used for 1000 Hz tympanometry for both the

normative and prospective portions of this study. Tympanometry was performed by presenting a

1 kHz probe tone at 85 dB SPL into the ear canal while air pressure changed from +200 to -400

daPa. The rate of pressure change was 600 daPa/sec on the tympanogram's positive and negative

tails. Rate of pressure change decreased to200 daPa/sec during peak admittance.

Calibration

Retrospective:

Calibration of the GSI 38 Automatic Tympanometer was performed annually between the

years 2007 and 2012.

Normative and Prospective:

Calibration of both the GSI 38 Automatic Tympanometer and the GSI TympStar Version

2 were performed prior to testing for this research study.

Results

Retrospective:

Otologic and 226 Hz tympanometry results were obtained via chart review for 151 individual participants. Out of these participants, 60 had multiple appointments, resulting in 151 unique participants and a total sample size of 238.

Data analyses included descriptive statistics mean, standard deviation, minimums and maximums and bivariate statistics of sensitivity, specificity, kappa, positive predictive value and negative predictive value. The minimum age for this portion of the study was 6 months and the maximum was 5 years six months, with a mean age of 2.05 years (Table 2). As for the gender make up of the participants, 52.1% were male and 47.9% were female (Table 3).

The current accepted static admittance value considered to be 'normal' for those older than six months of age is 0.3 mmhos (ASHA, 2004). However, because the audiologists and physicians had been seeing multiple instances of static admittance lower than the norm of 0.3 mmhos in the presence of normal middle ear status, it was decided to look at using lower cutoffs for 'normal' static admittance in this population. Even though 0.3 mmhos is accepted as the 'normal', we wondered what would happen to our analysis if we lowered the cutoff of 'normal' to 0.2 mmho or even 0.1 mmho. The goal in using multiple cutoffs for 'normal' was to determine which cutoff would give us the best sensitivity and specificity.

Sensitivity and specificity for the 226 Hz static admittance results in comparison to the otologic ear exam are shown in tables 7 and 8. Sensitivity is also known as the "true positive rate". This measurement refers to an 'abnormal' 226 Hz static admittance result in the presence of fluid in the middle ear space. Sensitivity tells us the percentage of time that the physician noted middle ear effusion and the audiologists also gathered 'abnormal' static admittance results,

as interpreted by the various cutoff values of 'normal'. The higher the percentage, the better the sensitivity. As the cutoff for normal is increased from 0.1 mmho to 0.3 mmhos, sensitivity increases meaning that a higher cutoff for 'normal' makes the 226 Hz tympanogram more accurate at determining the presence of pathology. The sensitivity measures were reasonable overall, indicating that the 226 Hz tympanogram is acceptable for determining the presence of middle ear pathology.

Specificity is known as the "true negative rate" and refers to 'normal' static admittance results in the presence of an air-filled middle ear space. Clinically speaking, specificity tells us the percentage that the physician noted an 'air-filled' middle ear space and the audiologist also had 'normal' static admittance results. It is evident that specificity measures are lower than sensitivity measures. The low specificity tells us that physicians would often make an otologic examination concluding the presence of 'air' in the middle ear space, with abnormal tympanometric results having been obtained by the audiologist. As the cutoffs for 'normal' static admittance become larger, going from 0.1 mmho to 0.3 mmho, specificity decreases. The highest specificity at the cutoff of 0.1 mmho of 57% tells us that a lower cutoff is more indicative of normal middle ear status with this population. This is concordant with what audiologists and physicians have noted clinically.

Kappa is a measure of agreement between two variables. A kappa value of 1 would indicate complete agreement while a kappa value of 0 would indicate no higher agreement than what would be expected by chance. The highest kappa value obtained was for the left ear with a cutoff for normal as 0.1 mmho, with a value of -.132 (Table 7). Even the highest kappa value still indicates very poor agreement between the 226 Hz static admittance result and the otoscopic examination.

Positive and negative predictive values were also calculated. It is important to keep in mind that these measurements are different from sensitivity and specificity, as they take into account the prevalence of fluid in the population. The positive predictive values indicate the percentage of flat tympanograms that actually were indicative of fluid. This answers the question of how predictive an 'abnormal' static admittance result was of abnormal middle ear status. Positive predictive values are low, indicating that a low static admittance was not always a good predictor of pathology.

Negative predictive values, indicate the percentage of peaked tympanograms in the presence of air in the middle ear space. Basically this measurement tells us how indicative a peaked tympanogram was of normal middle ear status. As the cutoff for normal increased from 0.1 mmho to 0.3 mmhos, the negative predictive value increased, showing that higher static admittance was more predictive of normal middle ear status. Comparing the positive and negative predictive values, it is clear to see that the negative predictive values are higher than positive predictive values. This indicates that a peaked tympanogram with 'normal' static admittance is often indicative of normal pathology.

Normative:

Normative 1000 Hz tympanometric data was compiled from 20 normal hearing individuals, making for an N of 40 ears. The minimum participant age was 2.57 years and the maximum was 29.59 years, with a mean age of 20.03 years (Table 2). The gender make-up of the participants was 30% male and 70% females (Table 4).

Data analyses included descriptive statistics mean, standard deviation, minimums, maximums, and percentiles including 5th and 95th for the 1000 Hz tympanometry values of

Ypc^{+200}, Ypc^{-200}, and $Ypc^{-400\ (Tail)}$. Data were analyzed using all 40 ears. The data were then compared to normative 1000 Hz tympanometry studies by Margolis et al. (2003) and Kei et al. (2003). The normative data from the aforementioned studies as well as the current study are shown in table 9.

Prospective:

Otologic exam, 226 Hz tympanometry, and 1000 Hz tympanometry results were obtained for 50 ears from 27 participants. Instances for exclusion of one of the ears included patent pressure equalization (PE) tubes, excessive amount of cerumen, active drainage, or too active to obtain reliable results during testing. The ages of the participants ranged from 1 year to 5.91 years, with a mean age of 2.81 years (Table 2). Of the participants, 48.1% were male and 51.9% were female (Table 5).

Static admittance results from the 226 Hz tympanogram were analyzed in the same fashion as the retrospective portion of the current study. However, due to the small N obtained for the prospective portion of the study, only the kappa values were determined. Right and left ears were looked at separately. Similar to the retrospective portion, kappa was low for this prospective portion of the study as well, with the largest kappa of .096 occurring at the right ear with 0.1 mmho as the cutoff for 'normal' (Table 11). This low kappa value, once again, indicates very poor agreement between the 226 Hz tympanogram and the otoscopic evaluation.

Ideally, descriptive statistics mean, standard deviation, minimums and maximums and bivariate statistics of sensitivity, specificity, kappa, positive predictive value and negative predictive value would have been determined for the 1000 Hz tympanometry values of Ypc^{+200}, Ypc^{-200}, and $Ypc^{-400\ (Tail)}$ in comparison the normative data. Our goal N was 80 ears, of which 40

would be 'air-filled' and 40 would be 'fluid-filled'. However, only 13 ears out of 50 were 'air-filled', making our sample size for the prospective portion of this study too small to calculate reliable and meaningful results.

Discussion

This study illustrates the need for a better standard of clinical practice to be used with the pediatric Down syndrome population in regards to determining presence or absence of middle ear effusion. Our results clearly indicate that the 226 Hz probe tone is not an accurate measure of middle ear effusion with this population. The study was divided into three distinct portions in order to address two main questions. The primary aim was to determine whether or not the current standard tympanogram used in those older than 6 months, i.e. the 226 Hz probe tone, is an accurate measure of middle ear effusion in children with Down syndrome. Additionally, we wanted to explore the 1000 Hz probe tone to determine whether or not it may be a better, more reliable tympanometric measurement to use with this population.

Data from the literature regarding tympanometry, pneumatic otoscopy and binocular microscopy in normally developing children indicates that there is no measure that can provide us with 100% sensitivity and specificity (Baldwin, 2006; Holte, Margolis & Cavanaugh, 1991). However, the determined values have proven to be high enough to validate the use of the 226 Hz tympanogram clinically. Studies regarding tympanometry in the Down syndrome population are extremely limited (Lewis, Bell, & Evans, 2011), calling for the need to investigate this population further.

Originally the data were analyzed with the 'indeterminate' otologic examinations considered to be 'abnormal' for the left and right ears, respectively. The data were then also analyzed using all data minus the 'indeterminate' ear examinations to see if there was a significant difference between the two. This was done because it was decided that the inability to make an assessment of the middle ear space does not necessarily indicate pathology. The data

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analyses did not change significantly based on the inclusion or exclusion of the 'indeterminate'

data. Therefore, the 'indeterminate' otologic exams were not included in analysis of the data.

For the retrospective review portion of this study, there were multiple discrepancies

between the physician's ear examination results and the 226 Hz static admittance values. The

most common discrepancy seen was an otologic finding of 'air-filled' in conjunction with a 'flat'

tympanogram. It was this repeated discrepancy, noted by both physicians and audiologists in

practice, which led to the birth of this project. This discrepancy can be easily illustrated when

looking at sensitivity and specificity measures. (Table 8) In general, the retrospective data in the

current study resulted in higher sensitivity in comparison to specificity. Sensitivity of 98.8% (for

both left and right ears) was achieved with a 0.3 mmhos cutoff for static admittance. This

indicates that the 226 tympanogram does predict the presence of fluid to a great degree.

Although the sensitivity was high, specificity was only 14% for the right ear and 23% for the left

ear, indicating that the 226 Hz tympanogram is not an accurate measure of predicting the

presence of air in the middle ear space.

To reiterate, the 0.3 mmhos value is the standard for a 'normal' tympanogram used in

pediatric populations (ASHA, 2004). Values less than 0.3 mmhos are most often determined as

'abnormal' by audiologists in clinical practice. However, with this population, as the cutoff for

'normal' was lowered towards 0 mmho for the 226 Hz tympanogram, sensitivity decreased and

specificity increased. This finding could indicate that a lower cutoff for 'normal' may need to be

determined for this population so that the absence of fluid could possibly be more accurately

determined.

The positive predictive values and negative predictive values for the retrospective portion

of this study should also be discussed. The negative predictive values were always higher than

the positive predictive values. When thinking about this, the high negative predictive values indicate that a peaked tympanogram was a very good prediction of an 'air' ear examination by the physician. The lower positive predictive values indicate that a flat tympanogram is not always a good predictor of fluid in the middle ear space. Additionally, with the different cutoffs for 'normal' static admittance, as the value increased towards 0.3 mmhos, the positive predictive value decreased and the negative predictive value increased. These values correlate with what was seen with the sensitivity and specificity results, as well as what has been seen clinically.

The retrospective portion of this study demonstrated what was hypothesized: the 226 Hz tympanogram is not an accurate measure of middle ear status with the Down syndrome population. The sensitivity, specificity, positive predictive values and negative predictive values indicate that the tympanometric results are not a good predictor of air in the middle ear space in comparison with the assumed "gold standard" for this study of pneumatic otoscopy or binocular microscopy. This finding is important, as the tympanogram is an important piece of information for the physician to use, especially with the difficulty visibility of the tympanic membrane in the stenotic ear canals of children with Down syndrome. The poor specificity of the 226 Hz tympanogram shows that the tympanogram may be over-diagnosing abnormalities of the middle ear space, when there, in fact, are none. The sample size for this portion was large enough to consider the findings of clinical significance. However, the next step was to determine whether or not there may be a "better" tympanometric measurement to use with this given population.

The 1000 Hz tympanometric probe tone was chosen as the experimental measurement for this study. Limited normative data is available on 1000 Hz probe tone tympanometry. Kei et al. (2003) and Margolis et al. (2003) have both determined 1000 Hz tympanometry norms in neonates. Clinical norms have not been determined, however, for 1000 Hz tympanometry in

children above six months of age. In order for our results from the prospective portion of this study to be valid, this normative data needed to be obtained. The mean age of our normative population (20.59 years), was much higher than the ages of the neonates in the published normative studies. Margolis et al. (2003) collected normative data from 105 ears in the neonatal intensive care unit (NICU) population, ranging in age from 23 weeks gestational age (GA) to 41 weeks GA in Table 1 of that study. Margolis et al. (2003) also collected normative data from 46 ears, ranging in age from 2-4 weeks chronological age (CA), found in Table 2 of that study. Kei et al (2003) compiled normative data for 212 ears of neonates with an average age of 3.29 days.

One of the challenges of the current study was determining which values of the 1000 Hz tympanogram that should be analyzed and compared. The common values used for interpretation by the normative studies were Y^{+200}, Y^{PEAK}, $Y^{-400(Tail)}$, YPC^{+200}, and $YPC^{-400(Tail)}$ (Kei et al., 2003; Margolis et al., 2003). Because the GSI TympStar Version 2 used for the 1000 Hz tympanometry in the current study produces unbaselined results, it was determined that the compensated measures would be the best for interpretation and comparison of the normative data. YPC^{+200} is the difference between Y^{PEAK} and Y^{+200} and $YPC^{-400\ (Tail)}$ is the difference between Y^{PEAK} and $Y^{-400\ (Tail)}$. Using the compensated measures reduces the variation in the baselined versus unbaselined admittance values.

Another challenge with the selection of values for the 1000 Hz tympanogram interpretation was determining how to classify a tympanogram as 'normal' or 'abnormal'. For both Margolis et al. (2003) and Kei et al. (2003), 5th and 95th percentile values were determined. For the sake of comparison, the same percentiles were determined for the data in the current study. Additionally, the Margolis et al. (2003) study did not provide ear specific data while Kei et al. (2003) and the current study included individual ear data. Normative data values for the

two aforementioned studies and the current study are shown in Table 8. When looking at the data of the two published normative studies compared to the current normative study, it is clear to see that the values for the current study are larger. This would be expected due to the age differences in the populations for the normative studies, with advanced maturation possibly causing increased static admittance in older populations. However, the goal was to distinguish which of the normative data worked the best with the 1000 Hz tympanometry data obtained in the Down syndrome population in the prospective portion of the study.

The sample size for the prospective portion of this study was 50 ears. These 50 ears had an otologic exam that determined the status of the middle ear space. With only the 'air' ear exams included, the N was 13 ears. This was not surprising, considering the high prevalence of middle ear effusion in the Down syndrome population. Also, participants were recruited on the same day of their audiology and ENT appointment. Many children visiting the clinic were a part of a multi-disciplinary team day of appointments for children with Down syndrome to provide continuing care. However, some of the children visiting the clinic were there due to current issues with their ears, possibly adding to the high number of 'fluid' otologic examinations.

The first step of the prospective portion of the study was to compare the results of the 226 Hz tympanogram to the otologic exam. Because the N was so small, only kappa was determined. The low kappa values for all static admittance cutoff values indicate poor agreement between the two tests. This statistic further confirms the conclusion reached from the retrospective chart review.

As for the 1000 Hz tympanometry values, the N was too small to come to any reliable conclusions on whether or not the high-frequency tympanogram actually might be a better measure of middle ear status with this population. A larger N needs to be obtained in order to

determine more conclusive results. A few cases of the preliminary data are discussed in the case studies.

Overall, the retrospective portion of this study indicates that the 226 Hz tympanogram is not a good measure of middle ear effusion to be used with the pediatric Down syndrome population. The quest to find a better tool to aid in determining middle ear status is still one that is yet to be completed. The 1000 Hz tympanogram may very well be a more accurate measure, however, we cannot determine this in the current study. A larger N would need to be compiled before coming to a solid conclusion on whether or not 1000 Hz tympanometry should be used with this population. Additionally normative data may need to be compiled in an age range that better matches the participants' age range. The normative data for this study may be too old for the population studied, and also has significantly more female participants than male. Although there are no significant tympanometric differences in regards to gender, future studies may want to compile normative data that is more equal between genders.

It is important to note as well that pneumatic otoscopy and/or binocular microscopy were the "gold standard" on determining middle ear status for this study. Binocular microscopy, however, has been shown to have higher specificity and sensitivity than pneumatic otoscopy alone (Rogers et. al., 2010). More than half of the participants in both the retrospective and prospective portions of this study had otologic exams using binocular microscopy (Table 6). The only true validation for an otologic examination, however, is myringotomy. Myringotomy is an invasive procedure and should not be performed unless clinically indicated. Therefore, it would not be ethical to use myringotomy as the "gold standard" for the purposes of this study.

Future directions for the current study include continuation of compilation of normative 1000 Hz tympanometry data in older populations. More work definitely needs to be done to

determine if there is a better tympanometric measure with the Down syndrome population.

Further data collection for the 1000 Hz tympanogram in Down syndrome should be collected.

Other high frequency tympanometric probe tones may also be explored.

<u>Conclusion</u>

Although the 226 Hz tympanogram has reasonable sensitivity and specificity for use in both pediatric and adult populations, this study shows that it is not as accurate a measure for children with Down syndrome, in regards to normative data being used clinically (ASHA, 2004). Further research needs to be completed to establish whether or not there is a more accurate tympanometric measure and what that might be so that Down syndrome patients can receive the highest standard of clinical care.

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Case Study 1

This is the case of a 1-year-old girl. In this instance, both the right and left ear 226 Hz tympanogram are flat, which is indicative of pathology. However, both the right and left ear 1000 Hz tympanometry results show a peak, indicative a normal middle ear function. Using the "gold standard" of otoscopy, the 226 would be considered a more accurate measure in this case, as presence of fluid and retracted tympanic membranes were reported in both ears.


Figure 2 – 226 Hz Tympanogram

Figure 3 – 1000 Hz Tympanogram
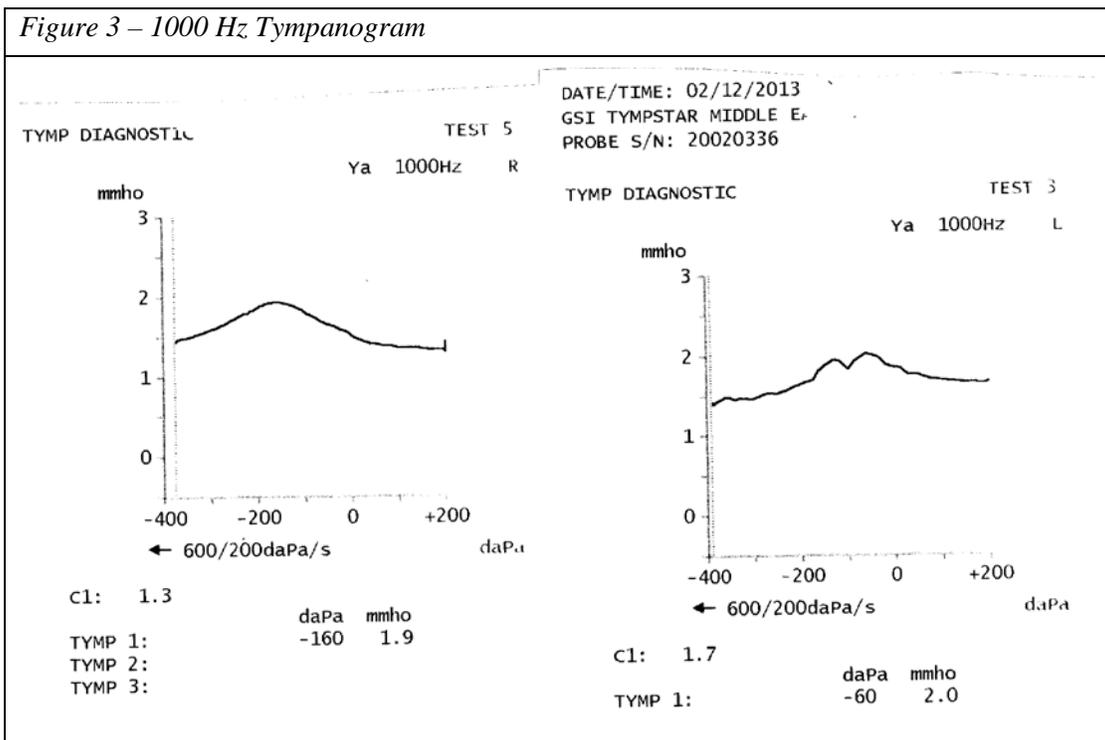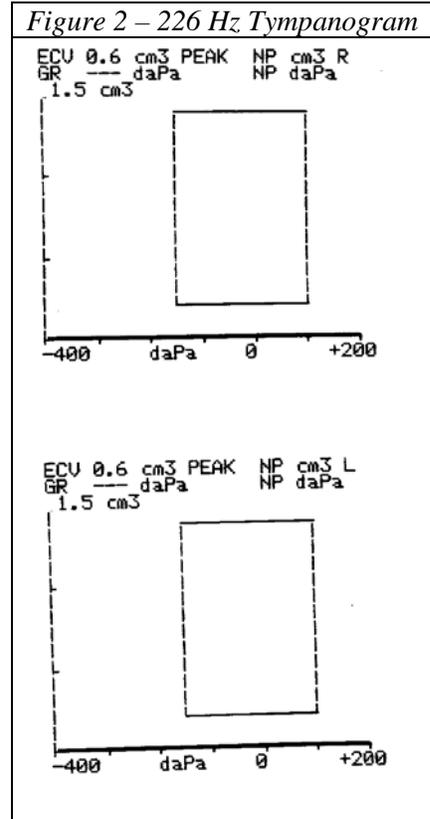
Case Study 2

Both pneumatic otoscopy and binocular microscopy were used for otologic examination with this 2.5-year-old boy. According to the 226 Hz tympanogram, the right ear static admittance would be within normal limits while the left ear static admittance would be considered abnormal. For the 1000 Hz tympanogram, both ears had tympanometric data that indicates normal middle ear function. However, note the 'W" configuration of the tracing. Vanhuyse, Creten, & van Camp (1975) further discuss the "W" notching of tympanograms, only occurring with high frequency probe tones. The nurse practitioner determined both ears to be "air-filled", with a retracted tympanic membrane on the left.

Figure 4 – 226 Hz Tympanogram


Figure 5 – 1000 Hz Tympanogram
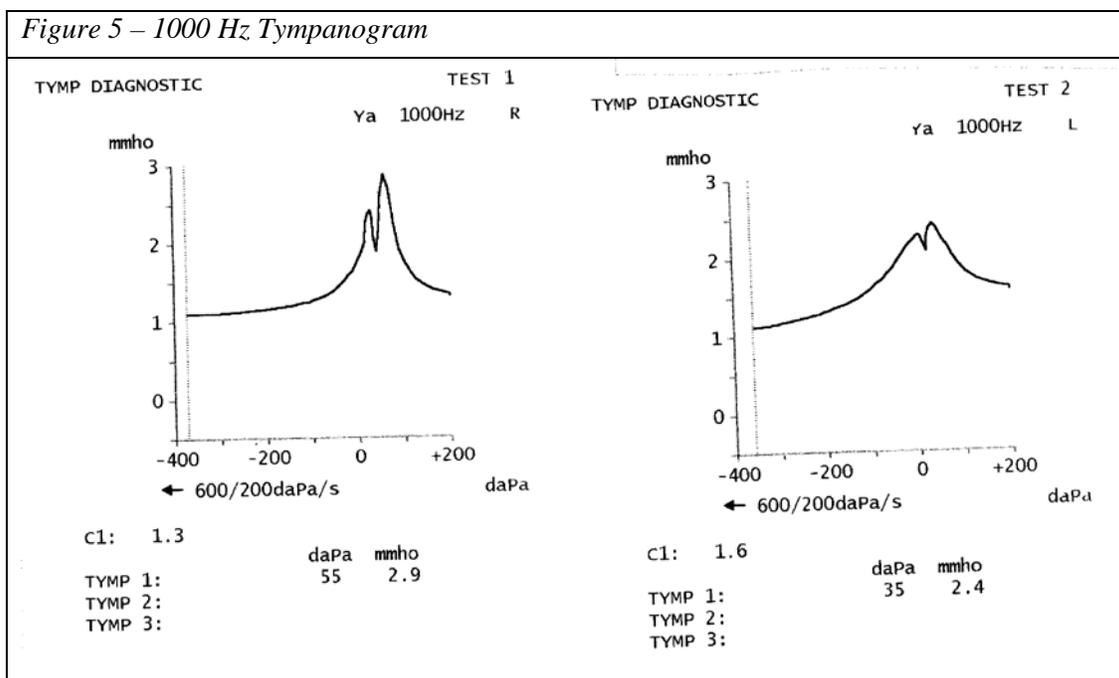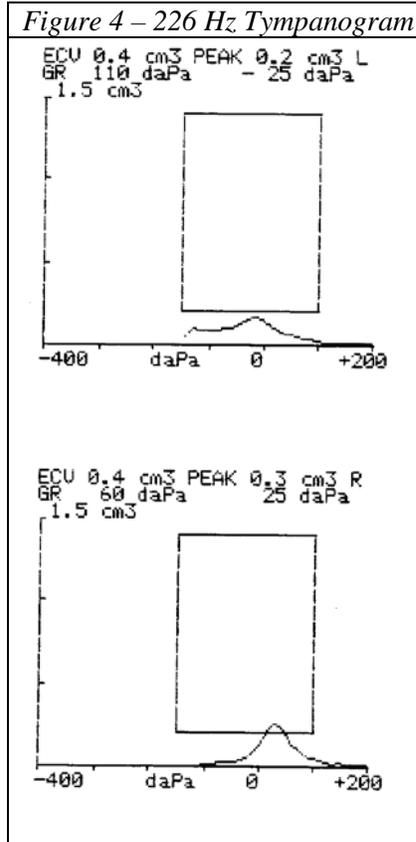
Case Study 3

This was a 2 year old girl seen for her annual multi-disciplinary appointment. The 226 Hz tympanogram is clearly indicative of pathology, having both low static admittance and negative middle ear pressure. The 1000 Hz peaked in both ears. Upon otologic exam, the physician determined that both middle ear spaces were filled with air through the use of pneumatic otoscopy. The physician noted that the tympanic membrane was thickened, but clearly mobile. In this case, the 1000 Hz tympanogram is a better predictive measure of the status of the middle ear.

Figure 6 – 226 Hz Tympanogram

Figure 7 – 1000 Hz Tympanogram
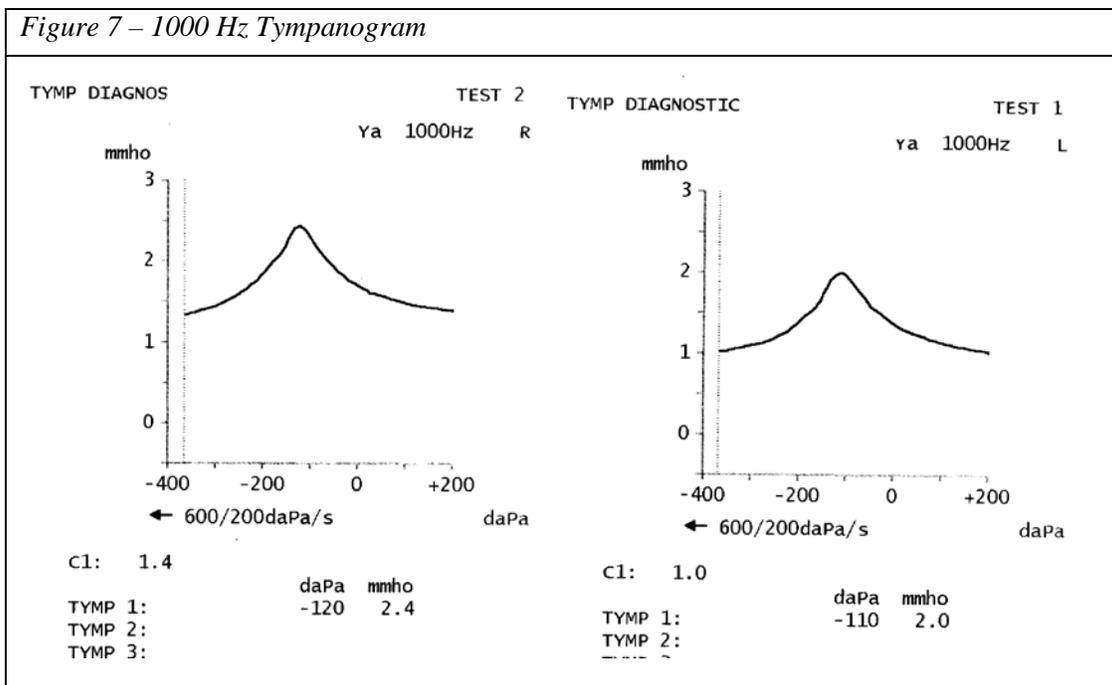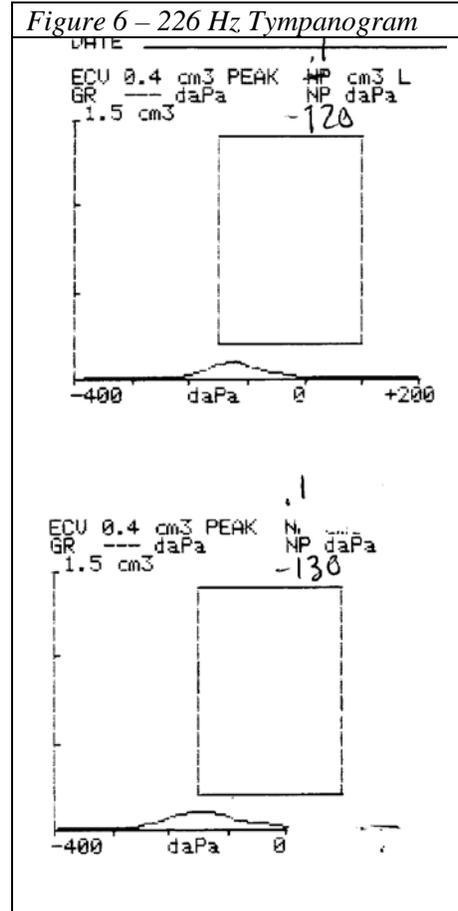
Case Study 4

This case involves a 2-year-old girl who was also seen as a part of her annual multidisciplinary check-up. Both right and left 226 Hz tympanometry data indicate poor mobility of the tympanic membrane. However, with the 1000 Hz tympanogram, the results from the right ear indicate normal middle ear function, while the left ear indicates possible middle ear pathology. The physician determined both middle ears to be filled with air. In this instance, the 1000 Hz tympanogram was a better measure of absence of fluid, even though it was just for one ear.

Figure 8 – 226 Hz Tympanogram

Figure 9 – 1000 Hz Tympanogram
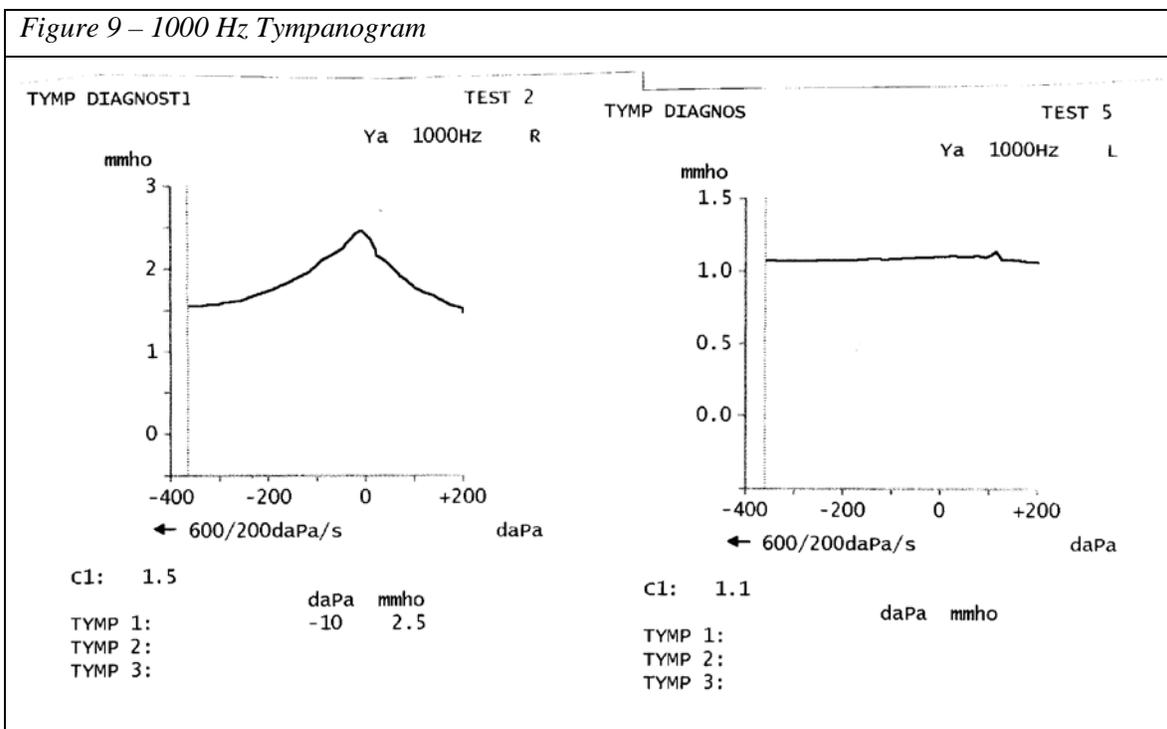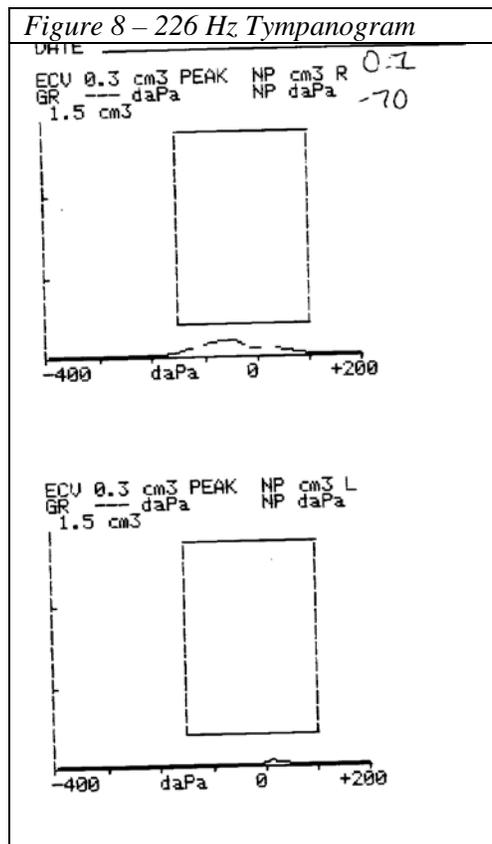
Table 2

Age (in years) Descriptive Statistics for the three portions of the current study						
Portion of Study	**N (ears)**	**N (participants)**	**Minimum**	**Maximum**	**Mean**	**Standard Deviation**
Retrospective	238	151	.55	5.47	2.05	1.10
Normative	40	20	2.57	29.59	20.0	9.08
Prospective	50	27	1.00	5.91	2.81	1.45

Table 3

Gender Descriptive Statistics for Retrospective Data Collection by Participant, not ears				
Gender	**Frequency**	**Percentage**	**Mean Age (in years)**	**Standard Deviation**
Male	124	52.1%	2.039	1.08
Female	114	47.9%	2.0674	1.12

Table 4

Gender Descriptive Statistics for Normative Data Collection by Participant, not ears				
Gender	**Frequency**	**Percentage**	**Mean Age (in years)**	**Standard Deviation**
Male	6	30%	20.20	10.37
Female	14	70%	19.99	8.89

Table 5

Gender Descriptive Statistics for Prospective Data Collection, by participant, not ears				
Gender	**Frequency**	**Percentage**	**Mean Age (in years)**	**Standard Deviation**
Male	13	48.1%	2.64	1.42
Female	14	51.9%	2.98	1.51

Table 6

Percentages of Otoscope Used for Retrospective and Prospective portions of the current study				
Portion of Study	**Pneumatic Otoscope**	**Binocular Microscope**	**Both Binocular Microscope and Pneumatic Otoscope**	**Unknown/Other**
Retrospective	16%	22.3%	41.6%	17.6%
Prospective	18.5%	59.3%	18.5%	3.7%

Table 7

Left Ear Retrospective 226 Hz Static Admittance Data					
Cutoff for 'Normal'	Sensitivity	Specificity	Kappa	Positive Predictive Value	Negative Predictive Value
.1 mmho	90.4%	57.4%	-.132	56.4%	90.7%
.2 mmhos	92.8%	47.8%	-.109	52%	91.5%
.3 mmhos	98.8%	23%	-.054	44.1%	96.8%

Table 8

Right Ear Retrospective 226 Hz Static Admittance Data					
Cutoff for 'Normal'	Sensitivity	Specificity	Kappa	Positive Predictive Value	Negative Predictive Value
.1 mmho	88%	51.9%	-.111	54.1%	87%
.2 mmhos	95.2%	39.5%	-.092	50.3%	92.7%
.3 mmhos	98.8%	14%	-.031	42.5%	94.7%

Table 9

Normative 1000 Hz tympanometry data						
Normative Study	Variable	N (ears)	Mean	SD	5th Percentile	95th Percentile
Margolis, et al., 2003 – Table 1	Ypc^{+200}	105	0.8	0.5	0.2	1.60
	$Ypc^{-400(Tail)}$	105	1.5	0.7	0.6	2.70
Margolis et al., 2003 – Table 2	Ypc^{+200}	46	1.3	1.0	0.1	3.50
	$Ypc^{-400(Tail)}$	46	1.9	1.3	0.6	4.30
Kei et al., 2003 – Left Ear	Ypc^{+200}	106	1.04	0.51	0.39	1.95
Kei et al., 2003 – Right Ear	Ypc^{+200}	106	1.16	0.58	0.39	2.28
Current Study – Left Ear	Ypc^{+200}	20	1.96	1.074	0.61	4.20
	Ypc^{-200}	20	2.4805	1.205	0.79	5.46
	$Ypc^{-400(Tail)}$	20	2.772	1.21	1.147	5.56
Current Study – Right Ear	Ypc^{+200}	20	2.135	1.21	0.805	5.17
	Ypc^{-200}	20	2.519	1.335	0.912	6.11
	$Ypc^{-400(Tail)}$	20	2.818	1.369	1.091	6.35

Table 10

Left Ear Prospective 226 Hz Kappa Values	
Cutoff for 'Normal'	Kappa
.1 mmho	-.079
.2 mmhos	.000
.3 mmhos	.012

Table 11

Right Ear Prospective 226 Hz Kappa Values	
Cutoff for 'Normal'	**Kappa**
.1 mmho	-.096
.2 mmhos	-.031
.3 mmhos	-.045