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Efficacy of high-frequency tympanometry in infants birth to six months of age: A pilot study

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EFFICACY OF HIGH-FREQUENCY TYMPANOMETRY IN INFANTS BIRTH TO SIX MONTHS OF AGE: A PILOT STUDY

by

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Abstract: The purpose of this study was to assess the use of 1 kHz tympanometry in young infants. A larger sample will be needed to develop definitive norms and determine the sensitivity and specificity of 1 kHz tympanometry for middle ear pathology in young infants.

Acknowledgments

I appreciate the audiology and otolaryngology departments of St. Louis Children's Hospital for allowing me to participate in this research project. To the doctors, clinicians, and support staff who donated their time to this effort. To the members of the audiology community who took the time to answer my questions about their research. Below is an alphabetical list of those who I would like to thank.

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Introduction

The advent of universal newborn hearing screening (UNHS) has led to the early identification of hearing loss. Audiologists are now faced with the goal of diagnosing the type and severity of an infant's hearing loss by three months of age (JCIH, 2007). The most common cause of referral on UNHS is conductive hearing loss, the majority of which is secondary to otitis media or middle ear effusion (Boone, Bower, & Martin, 2005; Doyle, Burggraff, Fujikawa, & Macarthur, 1997). Assessing middle ear status is difficult in young infants for both the audiologist and otolaryngologist (Bluestone & Klein, 2007; Watkin & Baldwin, 1999). The audiologist has bone conduction auditory brainstem response (ABR) and high-frequency tympanometry to facilitate diagnosis of the conductive component. The otolaryngologist has pneumatic otoscopy and/or otomicroscopy to determine presence or absence of middle ear effusion. None of these tools is perfect and it is reassuring to both the physician and the audiologist when audiologic results and otologic findings are in agreement.

Tympanometry

Conventional tympanometry (226 Hz probe tone) provides a significant contribution to the assessment of middle ear status in patients older than seven months of age (Katz, 2002). Tympanometry is a quick, safe, and objective test of the middle ear system's ability to conduct sound. It also has a high completion rate in young infants. Pamlu, Puhkka, Rahko, and Takala (1999) recorded a 97% rate of completion for tympanometry in 115 infants under seven months of age. Engel, Anteunis, Chenault, and Marres (2000) also found a high completion rate of 89-94% in young infants from birth to six months of age. Conventional tympanometry's sensitivity in patients over seven months of age is 79% to 98.9% (see Table 1). Its specificity can range from 0% to 100% (see Table 2). However, for infants under seven months of age, 226 Hz

tympanometry produces both false negative and false positive tympanograms (Alaerts, Luts, & Wouters, 2007; Baldwin, 2006; Keefe & Levi, 1996; Paradise, Smith, & Bluestone, 1976; Pestalozza & Cusmano, 1980; Poulsen, & Tos, 1978; Rhodes, Margolis, Hirsch, & Napp, 1999; Schwartz & Schwartz, 1980; Shurin, Pelton, & Klein, 1976; Shurin, Pelton, & Finkelstein, 1977). This is due to the development of the infant's external and middle ear. Infants have a lower middle ear resonance than that of a mature middle ear system (Meyer, Jardine, & Deverson, 1997). The developing middle ear system is mass dominant due to several anatomical factors: cartilaginous ossicles, tympanic annulus, and external ear canal, mesenchyme in the middle ear cavity, and a less stiff ossicular connection between the tympanic membrane and the cochlea (Eby & Nadol, 1986; Keefe & Levi, 1996; Meyer, Jardine, & Deverson, 1997).

Table 1. Sensitivity of 226 Hz tympanometry in subjects older than 7 months of age.

226 Hz Tympanometry	Sensitivity	N	Source
	80.2%	N=81 ears	(Mills, 1986)
	89%	N=222 ears	(Toner & Mains, 1990)
	90%	N=163 ears	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	83%	N=515 ears	(Sassen, Aarem, & Grote, 1993)
	79%	N=113 ears	(Palmu, Puhakka, Pahko, & Takala, 1999)
	89.4%	N=201 ears	(Shiao & Guo, 2004)
	87.5%	N=85 ears	(Lee & Yeo, 2004)
	80%	N=35 ears	(Harris, Hutchinson, & Moravec, 2005)
	98.9 %	N=121 ears	(KC, Guragain, & Sinha, 2007)

Table 2. Specificity of 226 Hz tympanometry in subjects older than 7 months of age.

226 Hz Tympanometry	Specificity	N	Source
	98.8%	N=81 ears	(Mills, 1986)
	93%	N=222 ears	(Toner & Mains, 1990)
	86%	N=163 ears	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	63%	N=515 ears	(Sassen, Aarem, & Grote, 1993) "is rather low…could be an affect of anesthesia", p. 118
	99%	N=113 ears	(Palmu, Puhakka, Pahko, & Takala, 1999)
	81.8%	N=201 ears	(Shiao & Guo, 2004)
	0 %	N=85 ears	(Lee & Yeo, 2004)
	100%	N=35 ears	(Harris, Hutchinson, & Moravec, 2005)
	14.8%	N=121 ears	(KC, Guragain, & Sinha, 2007)

Infants younger than six to seven months of age require a high-frequency probe tone to produce valid results (Alaerts et al., 2007; Baldwin, 2006; Keefe & Levi, 1996; Paradise et al., 1976; Pestalozza & Cusmano, 1980; Poulsen, & Tos, 1978; Rhodes et al., 1999; Schwartz & Schwartz, 1980; Shurin et al., 1976; Shurin et al., 1977). Although high-frequency tympanometry with young infants was introduced thirty years ago (Paradise et al., 1976; Shurin et al., 1976; Shurin et al., 1977), clinical application of high-frequency tympanometry did not evolve until the 1990's with implementation of UNHS. With hearing screening referrals, came diagnostic audiologic assessment of infants by three months of age.

Both the Joint Committee on Infant Hearing (2007) and the American Speech-Language Hearing Association (2004) recommend high-frequency tympanometry for infants from birth to six months of age. Several high-frequency probe tones have been studied (e.g. 660 Hz, 880 Hz,

and 1000 Hz). Recently, research has centered on a 1 kHz probe tone which is currently the highest frequency available on commercial clinical tympanometers (Purdy & Williams, 2000). This stimulus has been shown to be more valid than other high-frequency probe tones (e.g. 660 Hz & 678 Hz) in studies by Baldwin (2006), Rhodes et al. (1999), and Williams et al. (1995).

Several normative studies on 1 kHz tympanometry have been published (Kei, Allison-Levick, Dockray, Harrys, Kirkegard, Wong, Maurer, Hegarty, Young, & Tudehope, 2003; Margolis, Bass-Rindahl, Hanks, Holte, & Zapala, 2003; Mazlan, Kei, Hickson, Stapleton, Grant, Lim, Linning, & Gavranich, 2007; Swanepoel, Werner, Hugo, Louw, Owen, & Swanepoel, 2007). One study noted the specificity of 1 kHz tympanometry as 95% (Swanepoel et al., 2007). Differences in static admittance based on gender, left vs. right ear, and age have been noted (Swanepoel et al., 2007; Kei, et al. 2003; Mazlan et al., 2007). However, the use of these norms clinically is problematic for at least two reasons. First, test parameters such as pump speed and compensated versus uncompensated tympanograms are not standardized. Second, it is not clear how development affects the need for age specific norms based on chronological age in weeks or months. Also, limited data are available correlating the results of 1 kHz tympanometry with medically diagnosed middle ear pathology (Williams et al., 1995). Appendix A contains a history of tympanometry.

Bone Conduction ABR

Bone conduction ABR can also be used to diagnose a conductive component. However, obtaining definitive bone conduction ABR thresholds on infants tested during natural sleep is often difficult. Bone conduction ABR was successfully performed on 42% to 47% of young infants assessed in studies by Andrews, Chorbachi, Sirimanna, Commerlad & Hartley (2004) and Karzon and Lieu (2006).

Otologic Examination of Young Infants

The current standard for diagnosing otitis media is pneumatic otoscopy (Alper, Bluestone, Casselbrant, Dohar, & Mandel, 2004). The diagnostic accuracy of this procedure is affected by the anatomy of the young infant's ear, the medical professional's training, and the equipment used to visualize the tympanic membrane.

The developmental anatomy of the external auditory canal, tympanic membrane, and middle ear makes otologic examination of infants less than seven months the most difficult of any age group. Infant anatomy includes collapsing external auditory canals, an angled tympanic membrane, and normal tympanic membrane characteristics that are identical to signs of otitis media (Cavanaugh, 1987). See Appendix B for a review of these characteristics.

With respect to the accuracy of the otologic examination, Pichichero and Poole (2001) compared the ability of general practitioners, pediatricians and otolaryngologists to identify normal middle ear status, versus middle ear effusion or acute otitis media (AOM) in infants and young children. Nine video recorded pneumatic otoendoscopic exams were performed on subjects, "most [of whom] were under two years" of age (Pichichero, personal communication, January, 14 2008). The average accuracy score for general practitioners was 45%. The score for pediatricians was 50%. For otolaryngologists, the score was 73%. Primary care doctors reported an average of 58% certainty in their diagnosis of AOM in infants under a year of age (Froom, Culpepper, Grob, Bartelds, Bowers, Bridges-Webb, Grava-Gubins, Green, Lion, Somaini, Stroobant, West, and Yodfat, 1990).

It is possible that all medical professionals have lower accuracy in real world practice in comparison to a research protocol. This is due to a variety of real world issues that include less accurate visualization equipment, uncooperative infants, anxiety due to parental presence,

difficult infant anatomy, and debris in the ear canal (Engel et al., 2000; Pichichero, 2000). A large percentage of pediatricians routinely use standard otoscopy for ear examinations, not pneumatic otoscopy or otoendoscopy which were used in the research videos and have a higher diagnostic value (Nelson, 1988). Due to infant anatomy, diagnosing the presence or absence of effusion is more difficult in this population than in the fully developed ears of young children and adults (Pichichero, 2000). The videos also showed a full and complete visual examination with all appropriate insufflations performed to assess tympanic membrane mobility adequately. In young infants, it is less likely that they will remain still for the exam to be performed thoroughly (Pichichero, 2000). The research videos were also played on a large screen, in color, for an adequate period of time; this increased visualization of the tympanic membrane and allowed time for landmarks to be analyzed. The subjects' ear canals were also cleaned of wax which allowed a full view of the tympanic membrane.

Diagnostic accuracy of the otologic examination is also affected by the type of equipment used to visualize the tympanic membrane. The type of equipment used commonly correlates with the professional specialty of the otoscopist utilizing it (Engel, Anteunis, Volovics, Hendricks, & Marres, 1999). Otolaryngologists commonly use more advanced instruments and pediatricians commonly use static otoscopy which has "limited" ability to aid in diagnosis (Nelson, 1988; Sassen, Van Aarem, & Grote, 1993).

The instruments that can be used to perform an otologic examination are as follows: a static otoscope, a pneumatic otoscope, a video telescope, an otomicroscope, and an otoendoscope. Static otoscopy has the least sensitivity and specificity (KC, Guragain, & Sinha, 2007). Otomicroscopy has the highest sensitivity; and pneumatic otoscopy and video teleoscopy have the highest specificity (Harris, Hutchinson, & Moravec, 2005; Lee & Yeo, 2004). This can

be seen in Tables 3 and 4. Pneumatic otoscopy is the standard in diagnosing otitis media (Alper

et al., 2004). When a diagnosis can not be made with pneumatic otoscopy, otolaryngologists

typically advance and use otomicroscopy to assess middle ear status (AAFP, 2004).

Table 3. Sensitivity of instruments used in otologic examinations.

Instrument	Sensitivity	N	Source
Static Otoscopy	78.7 %	N=121 ears	(KC, Guragain, & Sinha, 2007)
Pneumatic Otoscopy	87.7 %	N=81 ears	(Mills,1986)
	93 %	N=163 ears	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	87 %	N=222 ears	(Toner & Mains, 1988)
	90.5 %	N=201 ears	(Shiao & Guo, 2004)
	97.2 %	N=85 ears	(Lee & Yeo, 2004)
	84.5 %	N=35 ears	(Harris, Hutchinson, & Moravec, 2005)
	90.40 %	N=121 ears	(KC, Guragain, & Sinha, 2007)
Video Teleoscopy	97.8 %	N=201 ears	(Shiao & Guo, 2004)
Otomicroscopy	100 %	N=85 ears	(Lee & Yeo, 2004)

Table 4. Specificity of instruments used in otologic examinations.

Instrument	Specificity	N	Source
Static Otoscopy	22.2 %	N=121 ears	(KC, Guragain, & Sinha, 2007)
Pneumatic Otoscopy	91.4 %	N=81 ears	(Mains, 1986)
	89 %	N=222 ears	(Toner & Mains, 1988)
	58 %	N=163 ears	(Finitzo, Friel-Patti, Chinn, & Brown, 1992)
	38.5 %	N=85 ears	(Lee & Yeo, 2004)
	77.3 %	N=201 ears	(Shiao & Guo, 2004)
	100 %	N=35 ears	(Harris, Hutchinson, & Moravec, 2005)
	33.3 %	N=121 ears	(KC, Guragain, & Sinha, 2007)
Video Teleoscopy	100 %	N=201 ears	(Shiao & Guo, 2004)
Otomicroscopy	61.5 %	N=85 ears	(Lee & Yeo, 2004)

Purpose

The present study was designed to evaluate the benefit of high-frequency tympanometry (1 kHz probe tone) in the middle ear assessment of infants birth to six months of age. The goals of the current study were as follows:

1.) Collect additional normative data for infants in the birth through six-month age range.

2.) Based on normative data collected in the current study and from the literature, ascertain whether there is a significant correlation between high-frequency tympanometric results and otologic findings.

Methods

Authorization to perform research on human subjects was received from the Washington University in St. Louis School of Medicine Human Research Protection Office on September 5th, 2007.

Participants

Research subjects from birth to six months of age were recruited from patients scheduled for a diagnostic ABR. Subjects were tested during natural sleep in the audiology department of St. Louis Children's Hospital.

Informed consent was obtained on twenty-nine subjects, three subjects were withdrawn due to facial rash contraindicating otoscopy (N=1), complicated medical history (N=1), and parental request to withdraw from the study (N=1). Data were collected on twenty-six subjects. Otologic examination and ABR thresholds were obtained successfully for all fifty-two ears. Tympanometry was successfully obtained on forty-seven of fifty-two ears. On two ears, it is unknown why the tympanogram could not be measured. Three ears were excluded from the data set due to artifact (N=1) or collapsing canals (N=2) affecting the tympanograms. The collapsing canals were diagnosed by the otolaryngologist. The final data set consisted of forty-seven ears, twenty-two were from females and twenty-five were from males. Chronological age ranged from one month and one day to three months and one day (mean age= 1.8 months; SD $\pm$ 13.8 days). All subjects were born full term.

Procedure

Research subjects received an otologic examination, high-frequency tympanometry, and ABR. The otoscopic examination was performed by a board certified otolaryngologist or the pediatric nurse practitioner who specializes in otolaryngology. Twenty-five of the twenty-six

research subjects received the otologic examination from a board certified otolaryngologist. One research subject received the otologic examination from the pediatric nurse practitioner. Three board certified otolaryngologists participated in the research. Their years of experience were as follows: twelve years, eight years, and six months. The pediatric nurse practitioner had worked in the pediatric otolaryngology department for five years and had a total of nineteen years of pediatric nursing experience. Results of the otologic examination were recorded on a descriptive form. Ear descriptions included *clear*, *fluid*, *fluid and air*, or *not determinable*. The form also had a section for comments and recommendations.

High-frequency tympanometry and ABR were performed or supervised by a licensed audiologist. The five audiologists had the following years of experience: thirty-five, twenty-five, twenty-four, nineteen, and eleven years. The recommended sleep ABR protocol is available in Appendix C.

The otologic exam was typically performed immediately prior to the ABR session. However, the otologic diagnosis from the otolaryngologist or pediatric nurse practitioner was not revealed to the audiologist until after the high-frequency tympanometry and ABR results were obtained. There were two exceptions for which the audiologist needed to know the results of the otologic examination to aid in prioritizing the test sequence. In this case the otologic results were made known to the audiologists prior to the audiologic assessment. On two occasions, due to scheduling issues, the otologic examination was performed earlier or later in the day.

Equipment

The GSI TympStar Version 2 was used for high-frequency tympanometry. 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 to 200 daPa/sec during peak admittance.

ABR was performed with a two-channel Nicolet Spirit. The Welch Allyn pneumatic otoscope was used for pneumatic otoscopy. The Storz E.N.T. microscope and Wild Heerbrugg E.N.T. microscope were used for otomicroscopy.

Calibration

Calibration of the GSI TympStar Version 2 occurred on 9.29.06 and 10.18.07. Calibration of the Nicolet Spirit occurred on 9.29.06 and 10.18.07. All audiologic calibration was performed by Gordon and Stowe Associates.

Data Analysis

Normative Data

Criteria to consider research data as normal included an otologic description of clear and ABR click thresholds of $\leq$ 20 dBnHL, tone burst thresholds at 500 Hz & 1000 Hz of $\leq$ 30 dBnHL, and tone burst thresholds at 2,000 Hz & 4,000 Hz of $\leq$ 20 dBnHL. One subject with known sensorineural hearing loss was accepted into the normal data set due to an otologic description of clear and bone conduction ABR consistent with sensorineural findings. Descriptive statistics were calculated for Ya^{+200}, Ya^{Peak}, Ya^{-Tail}, Ypc^{+200}, Ypc^{-200}, Ypc^{-Tail}, and peak pressure. Descriptive statistics include mean, standard deviation, range, minimum, maximum, N, 5th percentile, 50th percentile, and 95th percentile.

Tympanometric Analysis

In conventional 226 Hz tympanometry, the most common value used to rate the tympanogram is compensated peak admittance with compensation occurring at +200 daPa. There is currently no consensus on which immittance value should be used to rate 1 kHz

tympanograms. Published normative studies have measured multiple values of admittance. Therefore, this study also measured multiple admittance values along the pressure sweep. This allows the current study to be compared to previously published studies. In addition, when a standard is chosen, the data will already have been gathered for that admittance value.

Tympanogram terminology used in this article refers to compensated and uncompensated tympanograms, also known as baselined and unbaselined tympanograms, respectively. "Peak pressure" refers to the ear canal pressure at which maximum admittance occurs. Ya^{+200} refers to uncompensated admittance measured at +200 daPa ear canal pressure (see Figure 1). Ya^{Peak} refers to the maximum uncompensated admittance measured during the pressure sweep (see Figure 2). Ya^{-Tail} refers to the uncompensated admittance measured under negative air pressure at the end of the pressure sweep (see Figure 3). Ypc^{+200} refers to peak compensated admittance, with compensation occurring at the admittance value measured at +200 daPa ear canal pressure, (see Figure 4). Ypc^{-200} refers to peak compensated admittance, with compensation occurring at the admittance value measured at -200 daPa ear canal pressure, (see Figure 5). Ypc^{-Tail} refers to peak compensated admittance, with compensation occurring at the admittance value measured at approximately – 400 daPa ear canal pressure (see Figure 6).

Figure 1. Ya^{+200}.   *Figure 2.* Ya^{Peak}.   *Figure 3.* Ya^{-Tail}.
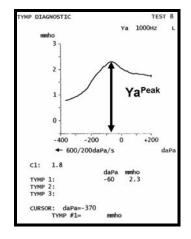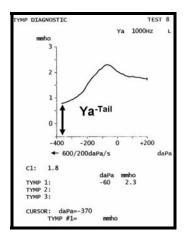
Figure 4. Ypc+200.　　　　*Figure 5*. Ypc-200.　　　　*Figure 6.* Ypc-Tail.
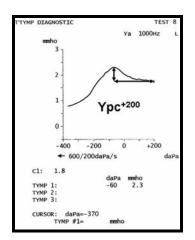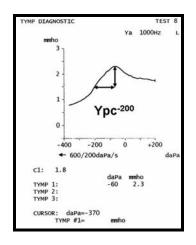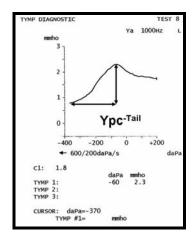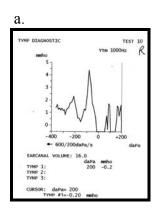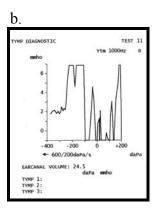
Results
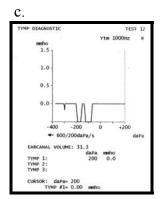
Success rate

Tympanometry with a 1 kHz probe tone was successfully obtained on 47 out of 52 ears, resulting in a success rate of 90.4% for young infants in a clinical setting. Two ears could not be tested for unknown reasons. Two ears had significant artifact (see Figures 7-8), potentially due to collapsing canals which were diagnosed by the otolaryngologist. One ear had artifact from infant movement and was not interpretable.

Figure 7. Right Ear Tympanograms with artifact potentially caused by collapsing canals, as diagnosed by the otolaryngologist.

a.　　　　b.　　　　c.　　　　d.
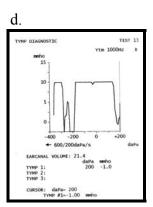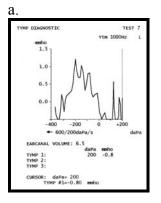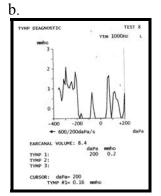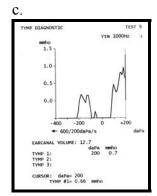
Figure 8. Left Ear Tympanograms with artifact potentially caused by collapsing canals, as diagnosed by the otolaryngologist.

a.

b.

c.

Normative Data

Thirty-four of the 47 ears met the criteria required for inclusion into the normative data set. Twenty-three of the subjects included in the normative data set had baselined tympanograms and therefore could not be included in the analysis of Ya^{+200}, Ya^{Peak}, or Ya^{-Tail}. Eleven subjects included in the normative data set had unbaselined tympanograms. As a result, norms for the uncompensated admittance values (Ya) had a sample size of 11. Tables 5-7 list the norms for each value.

Table 5.

Table 6.

Descriptive statistics for Ya^{+200} norms.	
Mean	1.58
Median	1.60
Standard Deviation	0.37
Sample Variance	0.14
Range	1.20
Minimum	1.10
Maximum	2.30
N	11
Percentile	Ya^{+200} *(mmho)*
95th	2.13
50th	1.60
5th	1.10

Descriptive statistics for Ya^{Peak} norms.	
Mean	2.56
Median	2.30
Standard Deviation	0.79
Sample Variance	0.63
Range	2.75
Minimum	1.70
Maximum	4.45
N	11
Percentile	Ya^{Peak} *(mmho)*
95th	3.83
50th	2.30
5th	1.80

Table 7.

Descriptive statistics for Ya $^{-Tail}$ norms.	
Mean	1.01
Median	0.93
Standard Deviation	0.42
Sample Variance	0.18
Range	1.51
Minimum	0.65
Maximum	2.16
N	11
Percentile	Ya $^{-Tail}$ (mmho)
95th	1.68
50th	0.93
5th	0.68

Measurement of Ypc^{+200}, Ypc^{-200}, Ypc^{-Tail}, and peak pressure required combining the baselined and unbaselined tympanograms. A t-test was performed for Ypc^{+200}, Ypc^{-200}, Ypc^{-Tail}, and peak pressure (see Appendix D). Results indicated no significant difference between baselined and unbaselined tympanograms; therefore, the data were pooled.

Measurement of Ypc^{+200} could be obtained from baselined and unbaselined tympanograms. All subjects in the normative data set could have this value measured, resulting in a sample size of 34 ears. See Table 8 for the norms for this value.

Measurement of Ypc^{-200} could be obtained from baselined and unbaselined tympanograms. Ten ears were excluded due to the negative tail dipping below the baseline and not being graphed, and due to the presence of artifact on the slope impeding accurate measurement of admittance at -200 daPa. This resulted in a sample size of 24 ears. Table 9 lists the norms for this value.

Table 8.

Descriptive statistics for baselined and unbaselined tympanograms: Ypc^{+200} norms.	
Mean	1.17
Median	0.91
Standard Deviation	0.95
Sample Variance	0.90
Range	4.29
Minimum	0.19
Maximum	4.48
N	34.00
Percentile	Ypc^{+200} mmho
95th	2.90
50th	0.91
5th	0.23

Table 9.

Descriptive statistics for baselined and unbaselined tympanograms: Ypc^{-200} norms.	
Mean	1.39
Median	1.19
Standard Deviation	0.86
Sample Variance	0.73
Range	3.70
Minimum	0.30
Maximum	4.00
N	24.00
Percentile	Ypc^{-200} mmho
95th	2.84
50th	1.19
5th	0.47

Measurement of Ypc^{-Tail} could be obtained from baselined and unbaselined

tympanograms. Eleven ears with baselined tympanograms were excluded due to the negative tail

dipping below the baseline and not being graphed. This resulted in a sample size of 23 ears.

Table 10 lists the norms for this value.

Measurement of peak pressure could be obtained from baselined and unbaselined

tympanograms. Therefore all 34 subjects in the normative data set were included in the analysis.

Table 11 lists the norms for this value.

Table 10.

Descriptive statistics for baselined and unbaselined tympanograms: Ypc^{-Tail} norms.	
Mean	1.65
Median	1.45
Standard Deviation	0.93
Sample Variance	0.87
Range	4.33

Table 11.

Descriptive statistics for peak pressure norms.	
Mean	-32.1
Median	-27.5
Standard Deviation	65.2
Sample Variance	4251.7
Range	290.0

Minimum	0.65
Maximum	4.98
N	23
Percentile	Ypc^{-Tail} (mmho)
95th	3.16
50th	1.45
5th	0.78

Minimum	-225.0
Maximum	65.0
N	34.0
Percentile	Peak Pressure (daPa)
95th	55.0
50th	-27.5
5th	-150.0

Correlation with Middle Ear Diagnosis

Five ears in the current study were diagnosed with fluid or fluid and air by the

otolaryngologist. Of the five abnormal ears, 1 kHz tympanometry, using this study's Ypc^{+200}

norms, rated three ears abnormal. Using the Ypc^{+200} norms from Margolis et al. (2003) resulted

in the same three tympanograms being labeled abnormal. The tympanograms were then rated by

three audiologists based on quick visual examination alone. This also resulted in the same three

tympanograms being labeled as abnormal (see Table 12).

Table 12. Subjects with otologic diagnosis of *fluid* or *fluid and air*.

Subject / Ear	ABR ▲	1 kHz Tymp ◘	1 kHz Tymp ♦	1 kHz Tymp●
10 R	Normal	Normal	Normal	Normal
10 L	Abnormal	Abnormal-Low	Abnormal-Low	Abnormal
17 R	Abnormal	Abnormal-Low	Abnormal-Low	Abnormal
17 L	Normal	Normal	Normal	Normal
18 R	Abnormal	Abnormal-Low	Abnormal-Low	Abnormal

▲ ABR rated as normal or abnormal based on this study's criteria, refer to p. 14.

◘ Tympanogram rated as normal or abnormal based on this study's 5th-95th percentile norms for Ypc^{+200} (see Table 17).

♦ Tympanogram rated as normal or abnormal based on Margolis et al.'s (2003) 5th-95th percentile norms for Ypc^{+200} (see Table 17).

● Tympanogram rated as *normal*, *abnormal*, *too much artifact to call*, or *not sure* based on visual examination by three audiologists who specialize in ABR. Ratings were based on the audiologist's sole judgment, they were blinded to the responses given by the other audiologists. For Table 12, no difference in rating occurred among the audiologists.

Forty ears in the current study received an otologic diagnosis of clear. Of the 40 ears, using this study's Ypc^{+200} norms, four were rated as abnormal. Using Ypc^{+200} norms from Margolis et al. (2003), resulted in only two ears being labeled abnormal. This is due to the 5th percentile of Ypc^{+200} norms from Margolis et al. (2003) being a lower admittance value than in the current study. The Margolis et al. (2003) 5th percentile was 0.1 mmho, while this study's 5th percentile was 0.23 mmho. Ears labeled as *Abnormal-High*, represented an admittance value that was greater than the 95th percentile. Ears labeled as *Abnormal-Low*, represented an admittance value that was less than the 5th percentile. The tympanograms were rated visually by the three audiologists resulted in four tympanograms being labeled as abnormal (see Table 13).

Table 13. Subjects with normal otologic, regardless of ABR thresholds.

Subject / Ear	ABR ▲	1 kHz Tymp ◘	1 kHz Tymp ♦	1 kHz Tymp●
1 R	Normal	Normal	Normal	Normal (3/3)
2 R	Normal	Normal	Normal	Normal (2/3)
2 L	Normal	Normal	Normal	Normal (3/3)
3 R	Normal	Abnormal-High	Abnormal-High	Normal (3/3)
3 L	Normal	Normal	Normal	Normal (3/3)
4 R	Normal	Normal	Normal	Normal (3/3)
4 L	Normal	Normal	Normal	Normal (3/3)
5 R	Normal	Normal	Normal	Normal (3/3)
5 L	Normal	Normal	Normal	Normal (3/3)
6 R	Normal	Normal	Normal	Normal (3/3)
6 L	Normal	Normal	Normal	Normal (3/3)
7 R	Normal	Abnormal-Low	Normal	*
7 L	Normal	Normal	Normal	Normal (3/3)
8 R	Normal	Normal	Normal	Normal (3/3)
8 L	Normal	Normal	Normal	Normal (3/3)
9 R	Normal	Normal	Normal	Normal (3/3)
9 L	Normal	Normal	Normal	Normal (3/3)
11 R	Abnormal	Abnormal-Low	Abnormal-Low	Abnormal (3/3)
11 L	Normal	Normal	Normal	Normal (3/3)
13 R	Abnormal -known SNHL	Normal	Normal	Normal (3/3)
13 L	Abnormal	Normal	Normal	*

—

	-known SNHL			
14 R	Normal	Normal	Normal	Normal (2/3)
14 L	Normal	Normal	Normal	Normal (3/3)
15 L	Normal	Normal	Normal	Normal (3/3)
16 R	Abnormal	Normal	Normal	Normal (3/3)
16 L	Abnormal	Normal	Normal	Abnormal (2/3)
18 L	Normal	Normal	Normal	Normal (2/3)
19 R	Abnormal	Normal	Normal	Normal (2/3)
19 L	Normal	Normal	Normal	Not Sure (2/3)
20 R	Normal	Normal	Normal	Normal (3/3)
20 L	Abnormal	Normal	Normal	Normal (3/3)
21 R	Normal	Normal	Normal	Abnormal (3/3)
21 L	Abnormal	Abnormal-Low	Normal	Abnormal (3/3)
22 L	Normal	Normal	Normal	*
23 R	Normal	Normal	Normal	Normal (3/3)
23 L	Normal	Normal	Normal	Normal (3/3)
24 R	Normal	Normal	Normal	Normal (3/3)
24 L	Normal	Normal	Normal	Normal (3/3)
25 R	Normal	Normal	Normal	Normal (3/3)
25 L	Normal	Normal	Normal	Normal (3/3)

Note.

▲ ABR rated as normal or abnormal based on this study's criteria, see p. 14.

◨ Tympanogram rated as normal or abnormal based on this study's 5th-95th percentile norms for Ypc^{+200} (see Table 17).

♦ Tympanogram rated as normal or abnormal based on Margolis et al.'s (2003) 5th-95th percentile norms for Ypc^{+200} (see Table 17).

● Tympanogram rated as *normal*, *abnormal*, *too much artifact to rate*, or *not sure* based on visual examination by three audiologists who specialize in ABR. The audiologists used their professional opinion, not published norms, to determine rating. Ratings were based on the audiologist's sole judgment; they were blinded to the responses given by the other audiologists. Final results were based on majority rating. **"(3/3)"** refers to all three audiologists giving the same rating. **"(2/3)"** refers to two out of three audiologists giving the same rating. **"*"** refers to no consensus, all ratings were different among the audiologists.

Case Studies

Three case studies were prepared to illustrate some of the issues involved with the

application of high-frequency tympanometry in early infancy. In case study 1, the right ear is an

example of how 1 kHz tympanometry, ABR, and the otologic examination correlate well,

indicating abnormal middle ear status. For the right ear, the high-frequency tympanogram has a

flat configuration which correlates well with the otologic diagnosis of fluid and abnormal ABR thresholds. A 226 Hz tympanogram was consecutively performed and a normal admittance value and configuration was obtained. This exemplifies how 226 Hz tympanograms are inaccurate in young infants, and can have a normal measure of admittance despite definite diagnosed pathology. The left ear is an example of how the three measures can correlate well with each other to agree on normal middle ear function.

Case Study # 1

Comparison of 1000 Hz vs. 226 Hz tympanometry.
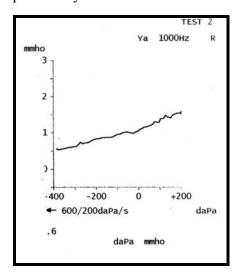
Subject 18, Right Ear
■ Otologic Exam

    ● Fluid

■ ABR Thresholds

    ● Click: 20 dBnHL
    ● 1 kHz Tone Burst: 50 dBnHL
    ● 4 kHz Tone Burst: 40 dBnHL

■ Tympanometry – 1 kHz Probe Tone
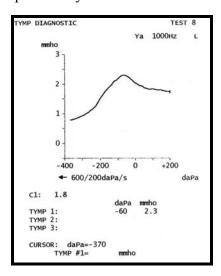
Subject 18, Left Ear
■ Otologic Exam
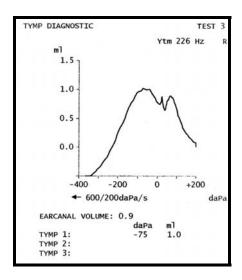
    ● Clear

■ ABR Thresholds

    ● Click: 20 dBnHL
    ● 1 kHz Tone Burst: 30 dBnHL
    ● 4 kHz Tone Burst: 20 dBnHL

■ Tympanometry – 1 kHz Probe Tone

■ Tympanometry – 226 Hz Probe Tone

In case study 2, the high-frequency tympanogram has a peak compensated admittance of 2.3 mmho in conjunction with an otologic diagnosis of fluid and normal ABR thresholds. In this example, the otologic diagnosis does not correlate well with the ABR thresholds and configuration of the high-frequency tympanogram. This could indicate that the otologic diagnosis was more sensitive to middle ear pathology than ABR or 1 kHz tympanometry. It is also possible that an otologic error occurred, illustrating the difficultly of performing an otologic examination on a young infant. In the left ear, an otologic diagnosis of fluid and air correlates well with the abnormal ABR thresholds and abnormal high-frequency tympanogram.

Case Study # 2

Right Ear: Normal 1 kHz tympanometry and ABR, with abnormal otologic exam.

Left Ear: Abnormal 1 kHz tympanometry and ABR, with normal otologic exam.
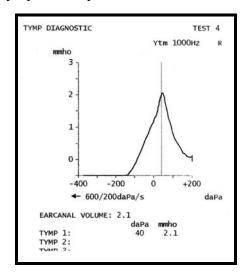
Subject 10, Right Ear
■ Otologic Exam

  ● Fluid

■ ABR Thresholds

  ● Click: 15 dBnHL
  ● 1 kHz Tone Burst: 30 dBnHL
  ● 4 kHz Tone Burst: 15 dBnHL
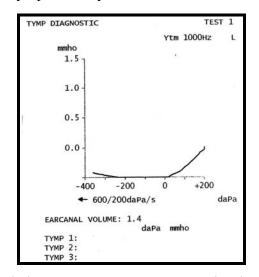
Subject 10, Left Ear
■ Otologic Exam

  ● Fluid and Air

■ ABR Thresholds

  ● Click: 20 dBnHL
  ● 1 kHz Tone Burst: 45 dBnHL
  ● 4 kHz Tone Burst: 20 dBnHL

■ Tympanometry – 1 kHz Probe Tone   ■ Tympanometry – 1 kHz Probe Tone

In case study 3, both ears had uncompensated 1kHz tympanograms measured. The

tympanograms were manually compensated at +200 daPa and a Ypc^{+200} value of 0.3 mmho was

calculated for the right ear, and 0.2 mmho for the left ear. An otologic diagnosis of clear was

given for both ears. Application of Ypc^{+200} norms from this study rated the right tympanogram

as normal and the left tympanogram as abnormal. Ypc^{+200} norms from Margolis et al. (2003)

rated both tympanograms as normal. However application of the third rating method, visual

inspection by expert audiologists, resulted in all three professionals rating the right and left

tympanograms as abnormal. One audiologist provided a comment describing the tympanograms

as having "low mobility". This case study is an example of how the range of normalcy in

tympanometry can have wide variability. Some individuals demonstrate results that are outside

the "normal range", but the results are not indicative of middle ear pathology. This illustrates the

idea that tympanometry is best used in a test battery or longitudinal fashion. If the clinician

knows the configuration of the infant's tympanogram when the ear is healthy, it might be more

clinically useful for the clinician to monitor a change in the infant's tympanogram values, rather

than to perform an absolute comparison to normative data. Intra-ear comparison is also useful in

determining if the tympanogram configuration is normal.

Wilson

Case Study # 3

**Normal otologic exam and ABR, with questionable tympanometry.**
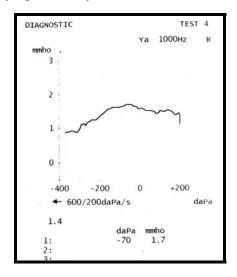
Subject 21, Right Ear
■ Otologic Exam

  ● Clear

■ ABR Thresholds

  ● Click: 15 dBnHL
  ● 1 kHz Tone Burst: 30 dBnHL
  ● 4 kHz Tone Burst: 20 dBnHL

■ Tympanometry – 1 kHz Probe Tone

Subject 21, Left Ear
■ Otologic Exam

  ● Clear

■ ABR Thresholds

  ● Click: 20 dBnHL
  ● 1 kHz Tone Burst: 50 dBnHL
  ● 4 kHz Tone Burst: 20 dBnHL

■ Tympanometry – 1 kHz Probe Tone

  ● 1.4 mmho= Ya at +200 daPa
  ● 1.7 mmho = Ya at -70 daPa, which
    is peak pressure
  ● 0.88 mmho = Ya at -370 daPa

  ● 1.4 mmho= Ya at +200 daPa
  ● 1.6 mmho = Ya at -95 daPa,
    which is peak pressure
  ● 0.8 mmho= Ya at -385 daPa

Discussion

The success rate of 1 kHz tympanometry was 90.4% in this study, which is similar to the

results of Kei et al. (2003) who obtained a success rate of 87.9%. Success rate was defined

differently between the current study and Kei et al. (2003). Success in the current study referred

to the ability to complete a tympanogram that had limited artifact which could interfere with

interpretation. Kei et al. (2003) defined success as the ability to maintain a hermetic seal during

tympanometry. Other normative studies did not discuss success rate of high-frequency tympanometry. Margolis et al. (2003) collected data via retrospective analysis; therefore, only subjects with completed tests were reviewed. Mazlan et al. (2007) and Swanepoel et al. (2007) did not specify the number of ears excluded based solely on inability to complete high-frequency tympanometry. Results of the current study indicate that high-frequency tympanometry has a success rate similar to conventional (226 Hz) tympanometry, with a 89-87% success rate in infants birth to three months of age (Engel et al., 2000).

Tables 14 through 20 provide a comparison of this study's normative data to other published norms for the following values: Ya^{+200}, Ya^{Peak}, Ypc^{+200}, Ypc^{-200} Ypc^{-Tail}, and peak pressure. The published norms include Kei et al. (2003), Margolis et al. (2003), Mazlan et al. (2007), and Swanepoel et al. (2007). None of the published norms used a tympanometry protocol identical to the current study. Differences in subject selection, instrumentation parameters and validation criteria were present among all of the studies reported.

Table 14. Comparison table for Ya^{+200}, units in mmho.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Kei et al. (2003)	212 ears (L + R)	Neonate	3.20 Left Ear 3.06 Right Ear	1.11 Left Ear 1.07 Right Ear	n/a	n/a	1.54 Left ear 1.40 Right ear	n/a	5.09 Left ear 5.01 Right ear
Margolis et al.(2003)	43 ears	2-4 wks	1.4	0.4	0.7	2.3	0.8	1.4	2.2
Mazlan et al. (2007)	40 ears	6-7 wks	1.33	0.41	0.62	2.78	n/a	n/a	n/a
Current Study	11 ears	4-12 wks	1.58	0.37	1.10	2.30	1.10	1.60	2.13

Table 15. Comparison table for Ya^{Peak}, units in mmho.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Margolis et al.(2003)	43 ears	2-4 wks	2.7	1.2	0.8	7.0	1.2	2.5	4.8
Mazlan et al. (2007)	40 ears	6-7 wks	2.35	0.71	1.16	4.50	n/a	n/a	n/a
Swanepoel et al. (2007)	177 ears	1-4 wks	2.4	0.7	1.2	5.1	1.5	2.3	3.8
Current Study	11 ears	4-12 wks	2.56	0.79	1.70	4.45	1.80	2.30	3.83

Table 16. Comparison table for Ya^{-Tail}, units in mmho.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Margolis et al.(2003)	43 ears	2-4 wks	0.8	0.4	0	1.7	0.3	0.8	1.4
Current Study	11 ears	4-12 wks	1.01	0.42	0.65	2.16	0.68	0.93	1.68

Table 17. Comparison table for Ypc^{+200}, units in mmho.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Kei et al. (2003)	212 ears (L + R)	Neonate	1.04 Left ear 1.16 Right ear	0.51 Left ear 0.58 Right ear	n/a	n/a	0.39 Left ear 0.39 Right ear	n/a	1.95 Left Ear 2.28 Right Ear
Margolis et al.(2003)	43 ears	2-4 wks	1.3	1.0	0	5.0	0.1	1.0	3.5
Mazlan et al. (2007)	40 ears	6-7 wks	1.01	0.52	0.35	2.58	n/a	n/a	n/a
Current Study	34 ears	4-12 wks	1.20	0.99	0.19	4.48	0.23	0.91	3.0

Table 18. Comparison table for Ypc^{-200}, units in mmho.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Kei et al. (2003)	212 ears	Neonate	2.13	0.77	n/a	n/a	0.13	n/a	3.54
Current Study	24 ears	4-12 wks	1.39	0.86	0.30	4.00	0.47	1.19	2.84

Table 19. Comparison table for Ypc^{-400}, units in mmho

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Margolis et al.(2003)	43 ears	2-4 wks	1.9	1.3	0.1	6.0	0.6	1.7	4.3
Current Study	23 ears	4-12 wks	1.65*	0.93*	0.65*	4.98*	0.78*	1.45*	3.16*

*Compensated at negative tail, the most negative point graphed on the tympanogram.

Table 20. Comparison table for Peak Pressure, units in daPa.

1kHz Norms	N	Infant Age	Mean	Standard Deviation	Min	Max	5th Percentile	50th Percentile	95th Percentile
Kei et al. (2003)	212 ears	Neonate	18.3	41.6	n/a	n/a	-58	n/a	86.6
Margolis et al.(2003)	43 ears	2-4 wks	-10	68	-200	200	-133	0	113
Mazlan et al. (2007)	40 ears	6-7 wks	-2.08	67.99	-254	80	n/a	n/a	n/a
Swanepoel et al. (2007)	177 ears	1-4 wks	5	49	-185	115	-80	5	85
Current Study	34 ears	4-12 wks	-32.1	65.2	-225.0	65.0	-150.0	-27.5	55.0

The published norms used otoacoustic emissions (OAEs) to aid in middle ear assessment.

In this study, the otologic examination in combination with ABR was used to validate normal

middle ear status. The age range of the test subjects differed among the studies as well. This

could affect the admittance values, which have been demonstrated to increase with age during infancy (Holte, Margolis, & Cavanaugh, 1991; Mazlan et al., 2007).

This study used a GSI TympStar Version 2. Swanepoel et al. (2007) also used the GSI TympStar Version 2; the other studies used different equipment. Research indicates equipment differences can affect measured values, specifically peak pressure (Gaihede & Marker, 1998).

Kei et al. (2003) used a +200 daPa to -200 daPa pressure sweep, while our study and other published norms used a +200 daPa to -400 daPa pressure sweep. A tympanogram with a -225 daPa peak pressure was included in the current study's norms. If a +200 to -200 pressure sweep had been used, this peak admittance would not have been captured. Therefore differences should be expected between normative studies with different pressure ranges.

The current study used a pump speed of 600 daPa/sec at the tails and 200 daPa/sec at the peak. Margolis et al. (2003) was the only study that used a similar pump rate. Pump rate can affect the measured admittance, with increased pump rate resulting in increased admittance (Katz, 2002). Swanepoel et al. (2007) used a 200 daPa/sec pump rate. This study used the same pump speed for the peak; however, the pump speed for the tails differed. This would affect the norms for peak to tail difference (Ypc^{+200} & Ypc^{-Tail}), resulting in a difference in norms from Swanepoel et al. (2007) in comparison to this study's norms. Kei et al. (2003) used a pump rate of 50 daPa/sec. Mazlan et al. (2007) used a pump rate of 400 daPa/sec.

Despite all the discrepancies noted above, this study's values for Y^{+200}, Y^{Peak}, and Y^{-400} are in the same range as values from other published normative data. However, expected characteristics such as increased admittance with an older subject population measured at higher pump rates were not seen when compared to studies with younger infants tested at slower pump

rates. This may be due to the small number of ears in the current study and/or to other procedural variables.

Norms for Ypc^{+200} were compared to Kei et al. (2003), Margolis et al. (2003), and Mazlan et al. (2007). Margolis et al. (2003) has the most similar tympanometric parameters to this study; therefore, their data were used for the main comparison. The Ypc^{+200} norms for mean, 5th percentile, and 95th percentile are similar: 1.20 mmho, 0.23 mmho, and 3.0 mmho, respectively for this study and 1.3 mmho, 0.1 mmho, and 3.5 mmho, respectively for Margolis et al. (2003).

This study's normative mean for Ypc^{-Tail} compared to Margolis et al (2003) is 0.25 mmho less (see Table 20). This could be due to our small sample size of 23 ears. Alternatively, it could be due to that fact that tympanometer used in this study rarely made the excursion fully to -400 daPa. It is not known whether the .25 mmho is statistically or clinically significant at this time.

Compared to the mean peak pressure of Kei et al. (2003), Margolis et al. (2003), Mazlan et al. (2007), and Swanepoel et al. (2007), this study's mean peak pressure was the most negative. This study's peak pressure values may have been influenced by the small sample size and/or procedural parameters (e.g., pump rate). Peak pressure in conventional 226 Hz tympanometry is the least diagnostic tympanometric value (Katz, 2002). Whether this is true for 1 kHz tympanometry is yet to be established. However, peak pressure is still clinically applicable due to the need to identify and monitor high negative middle ear pressure in infants (ASHA, 2004). It can add information about the status of middle ear effusion or infection, whether it is developing or resolving. Also, children with recurrent otitis media exhibit a higher prevalence of negative middle ear pressure, even during periods of resolution, than children without recurrent otitis media (Moody, Alper, & Doyle, 1998).

Trends noted in the published norms include a gender difference, a right to left ear difference, an increase in peak admittance as the infant ages, and a smaller Ypc^{+200} than Ypc^{-400} (Swanepoel et al., 2003; Kei et al., 2003; Mazlan et al., 2003; Margolis et al., 2003). Due to this study's small sample size, statistical analyses to assess the presence of the above trends would have limited significance and therefore, were not performed.

Formal measures of sensitivity and specificity were also not calculated due to the small sample size. A comparison of the three rating systems, noted in Tables 12 and 13, appear to indicate a reasonable correlation between methods. This provides an informal validation for the use of this study's norms, the norms from Margolis et al. (2003), or the clinician's professional judgment in assessing 1 kHz tympanograms.

Several weaknesses in this study are recognized and will be addressed in phase two of this research project. One limitation of this study was compensating the tympanograms during the first half of data collection. Automatic compensation of the tympanogram at +200 daPa by the tympanometer resulted in the loss of several data points (e.g Ya^{+200}, Ya^{Peak}, Ya^{-Tail}). For these measures, the Ypc^{-Tail} value was manually calculated from the printed tympanogram. It is unknown how much error this added to the calculated value. In addition, the Ypc^{-Tail} value could not always be measured with automatically compensated tympanograms because the admittance of the negative tail occasionally dipped below the baseline and was not graphed.

A second limitation concerns uncompensated tympanograms and the ability of the testers to insure that admittance values for Ya^{+200}, Ya^{Peak}, Ya^{-Tail} were printed on the tympanogram and remained present and legible after photo copying. In the current study, missing values were manually measured resulting in possible error in calculated admittance values.

A third limitation was the inconsistency of the tympanometer to record admittance to -

400 daPa. Swanepoel et al. (2007) also used the GSI TympStar Version 2 and reported that the sweep consistently ran from +200 to -400 daPa (personal communication, April 16, 2008). Communication with Grason Stadler, Inc. has yet to clarify the reason for this issue.

A fourth limitation was the presence of artifact affecting the measured admittance value at +200 daPa. This vertical artifact was seen with both compensated and uncompensated tympanograms. Artifact was occasionally large enough to warrant manual measurement of the admittance value at +200 daPa. Manual measurement of the +200 daPa value, when smaller artifact was present, was not performed due to the uncertainty of which would introduce more error, small vertical artifact or manual measurement. Dr. Swanepoel (personal communication, April 16, 2008) indicated that vertical artifact was not an issue his research team encountered. Both the failure to reach -400 daPa and the vertical artifact require further investigation with Grason Stadler Inc., equipment manufacturer.

A fifth limitation was the small sample size. A substantial number of ears are needed to provide definitive norms. This is especially true if there are developmental, ear, and gender effects. With respect to the second aim of this study, sensitivity of 1 kHz tympanograms, a significant number of ears with abnormal otologic exams must be recruited.

A sixth limitation of this study is the potential for minimal middle ear pathology despite normal results from the otologic examination and ABR evaluation. Negative middle ear pressure can often be undiagnosed by pneumatic otoscopy and ABR. It is recommended that diagnostic OAEs be added to the test battery. The sensitivity of OAEs to minimal middle ear pathology can aid in more accurately determining the correlation of high-frequency tympanometry to mild middle ear problems (Nozza, 2001). A seventh limitation was that daily calibration checks of the

GSI TympStar Version 2 were not performed. All published norms on 1 kHz tympanometry report daily calibration checks.

Conclusion

Despite a number of methodological differences, preliminary evidence with a small sample suggests that this study's norms are similar to those of previous investigators. Comparing the three rating methods used for 1 kHz tympanograms, preliminary results indicate similarity among the current study's norms, the norms of Margolis et al. (2003), and the professional judgment of experienced audiologists. The rate of completion for 1 kHz tympanometry in infants ranging from one to three months of age in a clinical setting was 90.4%. Both ASHA (2004) and JCIH (2007) recommend the addition of 1 kHz into the middle ear assessment battery. Determining the exact benefit of 1 kHz tympanometry in regard to its ability to refer infants with middle ear pathology is still needed. If 1 kHz tympanometry is sufficiently sensitive to middle ear pathology, standard protocols for administration and guidelines for interpretation will be needed to promote its widespread application in the clinical pediatric setting.

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Appendix A: History of Tympanometry

Although tympanometry was invented in the 1800's, widespread use did not occur until the mid 1900's (Katz, 2002). From a design by Zwislocki in 1963, a mechanoacoustic bridge was created that crossed over into standard clinical use with adults in the late 1960's (Katz, 2002). Tympanometry, using low-frequency probe tones, was first implemented with the pediatric population in the early 1970's (Brooks, 1971). The inconsistency of low-frequency tympanometry results for young infants became evident during research to develop standards for clinical application (Paradise, 1976; Shurin, 1976 & 1977).

Shurin et al. (1976) found that young infants (N=17) can have normal low-frequency tympanograms despite diagnosed middle ear effusion via otoscopy and or myringotomy. Paradise et al. (1976) compared tympanometry, pneumatic otoscopy, and myringotomy findings in 280 subjects ranging in age from ten days to five years. The results indicated that the accuracy of low-frequency tympanometry to detect middle ear effusion was affected by patient age. Infants under seven months of age often had normal low-frequency tympanograms despite a diagnosis of middle ear effusion via pneumatic otoscopy or post-myringotomy findings. However, low-frequency tympanometry in infants older than seven months was highly accurate. The results of Shurin et al. (1976) with 91 infants and children (two months to twelve years of age) indicated that low-frequency tympanometry had reduced validity in infants younger than four months of age.

The age at which low-frequency tympanometry became valid in infants differed between Paradise et al. (1976) and Shurin et al. (1977). Shurin et al. (1977) explained that this could be due to the different equipment used. Shurin et al. (1976, 1977) used an otoadmittance meter and Paradise et al. (1976) used an electroacoustic bridge.

Paradise et al. (1976) and Shurin et al. (1976, 1977) also performed high-frequency tympanometry on young infants and found it to be valid. Susceptance tympanograms using a high-frequency (660 Hz) tone correlated well with the middle ear diagnosis.

To support the findings of Shurin et al. (1977), Marchant, McMillan, Shurin, Johnson, Turczyk, Feinstein, and Panek (1986) studied 660 Hz susceptance tympanometry for infants under five months of age using an otoadmittance meter. The authors concluded that 660 Hz susceptance tympanometry was a valid measure of middle ear status in young infants.

Shurin et al. (1976, 1977) and Paradise et al. (1976) launched the use of high-frequency tympanometry in young infants. Their findings led to the agreement that low-frequency tympanometry produced false-negative tympanograms in young infants. The researchers also introduced the question concerning the exact age for which low-frequency tympanometry becomes valid in infants.

Multiple studies have followed, verifying the findings of Paradise et al. (1976) and Shurin et al. (1976, 1977) (Alaerts, Luts, & Wouters, 2007; Baldwin, 2006; Keefe & Levi, 1996; Paradise, Smith, & Bluestone, 1976; Pestalozza & Cusmano, 1980; Poulsen, & Tos, 1978; Rhodes, Margolis, Hirsch, & Napp, 1999; Schwartz & Schwartz, 1980; Shurin, Pelton, & Klein, 1976; Shurin, Pelton, & Finkelstein, 1977; Williams et al., 1995). In addition, Keefe and Levi (1996) noted the potential for false-positive responses with low-frequency tympanometry in young infants who have normal middle ear status.

Multi-Frequency Tympanometry:

With the knowledge that low-frequency tympanometry could not be used to identify the presence of effusion in young infants, researchers looked towards multi-frequency tympanometry. The first goal behind implementing multi-frequency tympanometry in young

infants was to analyze the maturation of the middle ear. Researchers wanted to find the age at which the infant middle ear system became adult-like and conventional (low-frequency) tympanometry could be used. The second goal was to determine the most accurate test frequency for performing high-frequency tympanometry in young infants by measuring the middle ear resonance of the infant (Meyer, Jardine, & Deverson, 1997).

Multi-frequency tympanometry is an umbrella term used to describe sweep tympanometry for frequencies 250 to 2000 Hz or the practice of obtaining two or three tympanograms, each with a different probe tone frequency. It has been used in adults and older children to determine a patient's middle ear resonance.

Multi-frequency tympanograms did not cross over into widespread clinical application. Difficulties in interpreting and classifying multi-frequency tympanograms hindered its use in the clinical setting (Hunter & Margolis, 1992).

In the fully mature middle ear system of children and adults, normal resonance occurs around 800-1200 Hz (Meyer et al., 1997). Meyer et al. (1997) chronicled the maturation of one infant's middle ear system using multi-frequency tympanometry. The middle ear resonance of the young infant was significantly lower in frequency than the resonant frequency of a mature middle ear system. This was caused by the dominance of mass in the infant's ear. In contrast, the adult middle ear is a stiffness-dominant system. As the anatomy of the infant's middle ear developed, stiffness became more dominant and resonant frequency increased (Meyer et al., 1997). By four months of age, the infant's middle ear resonance had reached the border of normal resonance by adult standards (Meyer et al., 1997). The resonance of the infant's middle ear continued to increase for another two months when it reached its final resonance value at six months of age (Meyer et al., 1997).

After learning about the maturation of the middle ear, researchers focused on finding the most valid high-frequency probe tone. High-frequency probe tones have progressed from 660 Hz to 1000 Hz. It is probable that researchers chose the highest probe tone frequency that was available on their tympanometer to perform their research (Purdy & Williams, 2000). As technology has progressed, tympanometers with increasingly higher probe tone frequencies have become commercially available (Mazlan et al., 2008).

Current Research

Research comparing 1 kHz to alternative high-frequency probe tones (e.g. 660 & 626 Hz) indicates 1 kHz provides fewer unclassifiable tympanograms and correlates better with other middle ear assessments (Baldwin, 2006; Rhodes et al., 1999; and Williams et al., 1995). Normative data have also been obtained using this stimulus (Kei et al., 2003; Margolis et al., 2003; Mazlan et al., 2007; Swanepoel et al., 2007), making any future research on the specificity and sensitivity of this measure more applicable if a 1 kHz probe tone is used.

Appendix B: Characteristics of the Infant's Tympanic Membrane

When determining middle ear status, four characteristics of the tympanic membrane are assessed. These characteristics include position, mobility, color, and translucency (Pichichero, 2000). In adults and older children, normal tympanic membrane characteristics and landmarks include the following: a neutral position (no distention or retraction), mobility resulting in 1 mm of displacement from insufflations, pearl gray in color, translucency, and thickness of approximately 0.074 mm. In addition, normal status correlates with visualization of the following: the cone of light, the umbo, the manubrium of the malleus, the long process of the incus, the annulus, the pars flaccida, and the pars tensa (Pichichero, 2000; Schwartz, 2007; Gelfand, 1997, p. 44).

Pathological characteristics of the tympanic membrane associated with otitis media are distension or retraction, decreased mobility, opacity, color including red, yellow, or dull gray, increased thickness, and inability to visualize landmarks such as the cone of light or the manubrium of the malleus (Pichichero, 2000). Unfortunately, due to the development of the outer and middle ear in the young infant, the characteristics of a normal middle ear in this population coincide with characteristics of otitis media (Cavanaugh, 1987). This makes the presence of pathology in infants difficult to differentiate from a normal tympanic membrane.

The normal characteristics of a young infant's tympanic membrane include decreased mobility, opacity, color that is pink, red, or a dull gray, increased thickness, and ability to visualize only a few landmarks such as the umbo, the manubrium, the short process of malleus, and a dim and smaller version of the cone of light. (Cavanaugh, 1987; Jaffe, Hurtado, & Hurtado 1969; McLellan & Webb, 1957; McLellan & Web, 1961). The normal position of the tympanic membrane was reported by McLellan et al. (1957) as being slightly retracted.

The orientation of the tympanic membrane in infants is also different than in adults. This is due to the cartilaginous structure of the ear canal which supports the tympanic membrane. In adults the tympanic membrane is almost completely vertical, is oval-shaped, and has more height than width. Bluestone & Klein (2007) describe the tympanic membrane of young infants as angled forward with the top half more externally oriented and the lower half more internally oriented. This causes the tympanic membrane to appear to have less height than it actually does. There is very little distinction between the end of the superior ear canal wall and the beginning of the tympanic membrane. This orientation, coupled with the opacity and limited mobility of the tympanic membrane and increased mobility of the ear canal walls, makes identification of the tympanic membrane and assessment of its mobility difficult. It is easy for a clinician to assess the mobility of the ear canal wall instead of the mobility of the tympanic membrane (Bluestone & Klein, 2007, p. 161; Jaffe et al., 1970).

A study by Cavanaugh (1987) chronicled the changes in tympanic membrane characteristics in infants. During the first days of life motility was inhibited in all sixteen ears visualized. By 42 to 69 days of age, 70% of infants (n=71) exhibited adequate tympanic membrane motility. During the first three days of life tympanic membrane color was pink in 33% of ears and gray in 60% of ears (n=81). By approximately ten weeks of age tympanic membrane color was pink in only 6% of ears, and gray in 90% of ears (n=71). During the first three days of life the characteristics of thickness, brilliance, and cone of light were categorized as adult-like in only 6%, 7%, and 4% of ears, respectively (n=115). By four months of age, the characteristics of thickness, brilliance, and cone of light were categorized as adult-like in 67%, 70%, and 67% of ears, respectively (n=30).

The orientation of the infant's tympanic membrane becomes more vertical as the inner portion of the external auditory canal ossifies. By one year of age the tympanic membrane is significantly more vertical; however, complete development into its adult form does not occur until around four and a half years of age (Eby & Nadol, 1986).

Appendix C: Recommended Sleep ABR Protocol
This protocol is based on a draft constructed by the SLCH audiology department.

Prior to ABR testing, administer high-frequency tympanometry on the infant. If high-frequency tympanometry cannot be successfully completed, continue with ABR testing and administer high-frequency tympanometry at the end of the ABR test session or as needed during the ABR test session.

Procedural outline for normal ABR bilaterally.

Step 1: Obtain click threshold for the ear with better hearing sensitivity, if known from screening results. This ear is now known as "Test Ear # 1". If the threshold obtained is normal, go to Step 2.

Step 2: In "Test Ear #1", obtain threshold using low or mid-frequency tone-burst stimuli (e.g. 500 Hz or 1,000 Hz). If the threshold is normal, go to Step 3.

Step 3: In "Test Ear # 1," obtain threshold using 4,000 Hz tone-burst stimuli. If the threshold obtained is normal, go to Step 4.

Step 4: Obtain click threshold for the opposite ear, this ear is now known as "Test Ear #2. If the threshold obtained is normal, go to Step 5.

Step 5: In "Test Ear #2", obtain threshold using low or mid-frequency tone-burst stimuli (e.g. 500 Hz or 1,000 Hz). If the threshold obtained is normal, go to Step 6.

Step 6: In "Test Ear # 2," obtain threshold using 4,000 Hz tone-burst stimuli. If the threshold obtained is normal, go to Step 7

Step 7: In "Test Ear #2", obtain thresholds using tone-burst stimuli for 2,000 Hz and the remaining test frequency of 500 Hz or 1,000 Hz (depending on which frequency was not used in Step 5). Which frequency to test first will depend on the infant's medical history and the clinician's ability to obtain results. After the thresholds are obtained, go to Step 8.

Step 8: Switch back to "Test Ear #1". Obtain thresholds using tone-burst stimuli for 2,000 Hz and the remaining test frequency of 500 Hz or 1,000 Hz (depending on which frequency was not used in Step 2). Which frequency to test first will depend on the infant's medical history and the clinician's ability to obtain results.

Clinical judgment determines how much time is spent trying to obtain thresholds using 500 Hz tone-burst stimuli.

Procedural outline for abnormal ABR bilaterally.

Step 1: Obtain click threshold for the ear with better hearing sensitivity, if known from screening results. This ear is now known as "Test Ear # 1". Obtain thresholds using click stimuli. If the threshold obtained is not normal (> 20 dBnHL), go to Step 2.

Step 2: Obtain click threshold in the opposite ear, this ear is now known as "Test Ear #2". Obtain threshold using click stimuli. If the threshold obtained is not normal (>20 dBnHL), go to Step 3.

Step 3: Attempt to obtain an unmasked bone conduction click threshold. Go to Step 4.

Step 4: If one ear has a better click threshold than the other, switch to the better ear and obtain thresholds using tone-burst stimuli for 1,000 Hz, 4,000 Hz, 2,000 Hz and 500 Hz, in that order. After obtaining all thresholds, go to Step 5.

Step 5: Obtain the remaining thresholds for the opposite ear (with the worse click threshold) using tone-burst stimuli for 1,000 Hz, 4,000 Hz, 2,000 Hz and 500 Hz, in that order. After obtaining these thresholds, go to Step 6.

Step 6: If high-frequency tympanograms are also normal, this case requires gathering as much audiologic and medical information as possible. Obtain frequency specific bone conduction thresholds and measure diagnostic DPOAEs.

Clinical judgment determines how much time is spent trying to obtain thresholds using 500 Hz tone-burst stimuli.

Procedural outline for a unilateral abnormal ABR: When testing starts in abnormal ear.

Step 1: Obtain click threshold for the ear with better hearing sensitivity, if known from screening results. This ear is now known as "Test Ear # 1". If the threshold obtained is not normal (>20 dBnHL), go to Step 2.

Step 2: Obtain click threshold for the opposite ear, this ear is now known as "Test Ear #2". If the threshold obtained is normal, go to Step 3.

Step 3: In "Test Ear #2", obtain threshold using low or mid-frequency tone-burst stimuli (e.g. 500 Hz or 1,000 Hz). If the threshold obtained is normal, go to Step 4.

Step 4: In "Test Ear # 2," obtain threshold using 4,000 Hz tone-burst stimuli. If the threshold obtained is normal, go to Step 5.

Step 5: In "Test Ear #2", obtain thresholds using tone-burst stimuli for 2,000 Hz first and then 500 Hz or 1,000 Hz (depending on which frequency was not used in Step 3). After the thresholds are obtained, go to Step 6.

Step 6: Switch testing back to "Test Ear #1" (the ear with the abnormal click threshold). Obtain threshold using 1,000 Hz and 4,000 Hz tone-burst stimuli, in that order. If the thresholds obtained are normal, go to Step 7. If the thresholds are abnormal (>20 dBnHL), go to Step 8.

Step 7: "Test Ear #1", obtain remaining thresholds for 2,000 Hz and 500 Hz tone-burst stimuli, in that order.

Step 8: Consider clinical value of obtaining remaining thresholds in the ear with abnormal thresholds.

Clinical judgment determines how much time is spent trying to obtain thresholds using 500 Hz tone-burst stimuli.

Procedural outline for a unilateral abnormal ABR: When testing starts in normal ear.

Step 1: Obtain click threshold for the ear with better hearing sensitivity, if known from screening results. This ear is now known as "Test Ear # 1". If the threshold obtained is normal, go to Step 2.

Step 2: In "Test Ear #1", obtain threshold using low or mid-frequency tone-burst stimuli (e.g. 500 Hz or 1,000 Hz). If threshold is normal, go to Step 3.

Step 3: In "Test Ear # 1," obtain threshold using 4,000 Hz tone-burst stimuli. If the threshold obtained is normal, go to Step 4.

Step 4: Obtain click threshold for the opposite ear, this ear is now known as "Test Ear #2". If the threshold obtained is normal, go to Step 5. If the threshold obtained is abnormal (>20 dBnHL), go to Step 7.

Step 5: In "Test Ear #2", obtain thresholds using low or mid-frequency tone-burst stimuli (e.g. 500 Hz or 1,000 Hz). If the thresholds obtained are normal, go to Step 6. If thresholds obtained are abnormal go to Step 7.

Step 6: In 'Test Ear #2", obtain thresholds using 4,000 Hz tone-burst stimuli. After threshold is obtained go to Step 7.

Step 7: Switch testing back to "Test Ear #1". Obtain thresholds using tone-burst stimuli for 2,000 Hz and the remaining test frequency of 500 Hz or 1,000 Hz (depending on which frequency was not used in Step 2). Which frequency to test first will depend on the infant's medical history and the clinician's ability to obtain results. After thresholds are obtained, go to Step 8.

Step 8: Consider clinical value of obtaining remaining thresholds in the ear with abnormal results.

Clinical judgment determines how much time is spent trying to obtain thresholds using 500 Hz tone-burst stimuli.

Appendix D
Statistical analysis to determine if data can be pooled.

Table 21 . Results of t-test: Can data set be pooled to calculate norms?

Tymp Values	p < 0.05 t-stat > t-crit	p > 0.05 t-stat < t-crit	Is a Statistical Difference Present?	Can Baselined & Unbaselined Tymps be Combined for Norms?
Ypc^{+200}		X	NO	YES
Ypc^{-200}		X	NO	YES
Ypc^{-Tail}		X	NO	YES
Peak Pressure		X	NO	YES

Table 22. Results of t-test for Ypc^{+200}.

Ypc^{+200}: Is there a significant difference between baselined and unbaselined tympanograms? t-Test: Two-Sample Assuming Equal Variances		
	Baselined Tymps	*Unbaselined*
Mean	1.26	0.97
Variance	1.05	0.61
Observations	23.00	11.00
Pooled Variance	0.91	
Hypothesized Mean Difference	0.00	
alpha	0.05	
df	32.00	
t Stat	0.83	
P(T<=t) two-tail	0.41	
t Critical two-tail	2.04	

Table 23. Results of t-test for Ypc^{-200}.

Ypc^{-200}: Is there a significant difference between baselined and unbaselined tympanograms?		
t-Test: Two-Sample Assuming Equal Variances		
	Baselined	*Unbaselined*
Mean	1.49	1.22
Variance	0.88	0.51
Observations	15.00	9.00
Pooled Variance	0.75	
Hypothesized Mean Difference	0.00	
alpha	0.05	
df	22.00	
t Stat	0.75	
P(T<=t) two-tail	0.46	
t Critical two-tail	2.07	

Table 24. Results of t-test for Ypc^{-Tail}.

Ypc^{-Tail}: Is there a significant difference between baselined and unbaselined tympanograms?		
t-Test: Two-Sample Assuming Equal Variances		
	Baselined	*Unbaselined*
Mean	1.74	1.55
Variance	1.29	0.48
Observations	12.00	11.00
Pooled Variance	0.90	
Hypothesized Mean Difference	0.00	
alpha	0.05	
df	21.00	
t Stat	0.49	
P(T<=t) two-tail	0.63	
t Critical two-tail	2.08	

Table 25. Results of t-test for peak pressure.

Peak Pressure: Is there a significant difference between baselined and unbaselined tympanograms? t-Test: Two-Sample Assuming Equal Variances		
	Baselined	*Unbaselined*
Mean	-25.22	-46.36
Variance	3564.72	5855.45
Observations	23.00	11.00
Pooled Variance	4280.58	
Hypothesized Mean Difference	0.00	
alpha	0.05	
df	32.00	
t Stat	0.88	
P(T<=t) two-tail	0.38	
t Critical two-tail	2.04	