J Am Acad Audiol 19:309–324 (2008)

Wideband Middle Ear Power Measurement in Infants and Children

DOI: 10.3766/jaaa.19.4.4

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Abstract

Wideband middle ear power (WMEP) measurement is a method of middle ear analysis that may provide improved diagnostic capability over single-frequency tympanometry. However, normative data, information about test–retest reliability, and results in clinical disorders are needed for clinical application. Normative and reliability data on WMEP in children three days to 47 months of age were obtained using a prototype commercial instrument. A prospective study was conducted in children enrolled from a well-child pediatric clinic (n = 97), with comparisons of age, gender, and middle ear status and stimulus type (broadband chirp and sine wave). No significant age effect for power reflectance across the age range of this study was found, except at 6000 Hz. Significantly higher-power reflectance was found for ears with poor ear status, specifically otitis media with effusion. Smaller but nonsignificant differences in power reflectance were found for ears with positive and negative tympanometric peak pressure. Intraclass correlation coefficients showed significant correlations of 0.68 to 0.97 at various test frequencies using the chirp stimulus. Multivariate analysis of variance showed no significant effect of stimulus type (sine wave vs broadband chirp), ear, or gender. These results provide normative data for wideband middle ear power analysis for infants and children from birth to age four years.

Key Words: Middle ear, otitis media, otoacoustic emissions, pediatrics, tympanometry

Abbreviations: DPOAE = distortion product otoacoustic emission; ICC = intraclass correlation coefficient; MEE = middle ear effusion; OAE = otoacoustic emission; OME = otitis media; SNR = signal-to-noise ratio; TPP = tympanometric peak pressure; WMEP = wideband middle ear power

Sumario

Las medidas de potencia de banda ancha del oído medio (WMEP) constituyen un método de análisis del oído medio que puede proveer una habilidad diagnóstica mejorada sobre la timpanometría de frecuencia

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This study was supported in part by Grant Number 1 R43 DC006554-01 from the National Institutes of Health, National Institute on Deafness and Other Communication Disorders.

única. Sin embargo y para su aplicación clínica, se necesitan datos normativos, información sobre confiabilidad test-retest y resultados en trastornos clínicos. Se obtuvieron datos normativos y de confiabilidad en WMEP en niños desde 3 días hasta 47 meses de edad, usando un instrumento prototipo comercial. Se condujo un estudio prospectivo en niños reclutados de una clínica pediátrica de niño sano (n = 97), realizando comparaciones de edad, género, y condición del oído medio y tipo de estímulo (gorjeo de banda ancha y onda sinusal). No se encontró un efecto significativo de la edad para la reflectancia de la potencia a lo largo del rango de edades en este estudio, excepto a 6000 Hz. Se encontraron reflectancias de potencia significativamente mayores en oídos con pobre condición, especialmente con otitis media con derrame. Se encontraron diferencias menores pero no significativas en la reflectancia de la potencia en oídos con picos de presión timpanométrica positivos y negativos. Los coeficientes de correlación intra-clase mostraron correlaciones significativas de 0.68 a 0.97, en varias frecuencias de prueba, utilizando estímulos de tipo gorjeo. Los análisis multivariados de varianza no mostraron efecto significativo según el tipo de estímulo (onda sinusal vs. gorjeo de banda ancha), del oído o del género. Estos resultados aportan datos normativos para el análisis de potencia de banda ancha del oído medio en infantes y niños desde el nacimiento hasta la edad de 4 años.

Palabras Clave: Oído medio, otitis media, emisiones otoacústicas, pediatría, timpanometría

Abreviaturas: DPOAE = emisiones otoacústicas por productos de distorsión; ICC = coeficiente de correlación intra-clase; MEE = derrame del oído medio; OAE = emisión otoacústica; OME = otitis media; SNR = tasa señal-ruido; TPP = pico de presión timpanométrica; WMEP = potencia de banda ancha del oído medio

It is important that effective and efficient diagnostic tools be available to help detect middle ear dysfunction for infants and children because of the high prevalence of middle ear effusion (MEE) in this age group. Timely and efficient diagnosis of middle ear dysfunction is particularly important in infants who have been referred after newborn hearing screening. Although newborn screening has become a standard of care, clinically validated tests for diagnosing middle ear dysfunction are not currently available for infants younger than six months (Hunter and Margolis, 1992; Keefe et al, 2003).

Conventional tympanometry is effective at detecting otitis media (OME) in children seven months and older, but its efficacy in infants six months and under is debatable due to the immaturity of infant outer and middle ears (Holte et al, 1991; Hunter and Margolis, 1992). Significant developmental changes in the physical properties of the newborn outer and middle ear occur over the first four to six months of life that affect tests of middle ear function (Holte et al, 1990). Thus, the lack of an accepted gold standard for middle ear disorders has hindered test validation in infants under six months of age.

Tympanometry at 226 Hz has been widely reported to be ineffective in detecting middle ear effusion in infants less than about six months of age (Paradise et al, 1976; Hunter and Margolis, 1992; Rhodes et al, 1999). Additionally, tympanometry is effective in a limited range of frequencies, and only low-frequency tympanometry (e.g., 226 Hz) is widely used clinically. There is ongoing debate regarding the frequency range at which tympanometry is most effective for detection of MEE in young infants. Holte and colleagues (1991) report that tympanometric patterns become less interpretable at higher frequencies; therefore, they suggest a probe tone of 226 Hz for infants below four months of age. Other investigators have found that 226 Hz tympanometry appeared normal in infants under seven months of age even when MEE was present, resulting in poor sensitivity for the diagnosis of middle ear pathology (Paradise et al, 1976; Balkany et al, 1978). Marchant and colleagues (1986) report that a probe tone of 660 Hz, as opposed to the more common 226 Hz probe frequency, was superior for prediction of OME (detected with myringotomy) in infants less than five months of age. This finding does not appear to have been replicated in a myringotomy or tube study. McKinley, Grose, and Roush (1997) found that multifrequency tympanometric patterns were more complex at low frequencies in newborns and also that 678 Hz tympanograms were flat in infants with absent otoacoustic emissions (OAEs). Conversely, Keefe, Bulen, Arehart, and Burns (1993) have suggested that 220–660 Hz is a poor frequency range to use for tympanometry with infants, due to significant ear canal wall motion and a resonant amplification of the wall motion in this frequency range. Rhodes and colleagues (1999) found that 1000 Hz tympanometry was more effective at detecting MEE in young infants than tympanometry at both 226 and 660 Hz. More recently, Kei and colleagues (2003) and Margolis and colleagues (2003) have reported normative ranges for 1000 Hz tympanometry in neonates between one and six days old and in neonatal intensive care unit and well babies, respectively. Thus, the literature at present is inconclusive with regard to the validity of tympanometry for detection of OME in newborns.

An important need for both infants and young children is discrimination of failed OAEs due to transient middle ear problems as opposed to sensorineural hearing loss. OAE screening may be affected by debris in the ear canal or middle ear material such as mesenchyme (Kasemsuwan et al, 1996; Piza et al, 1998; Jaisinghani et al, 1999), meconium contamination (Piza et al, 1989), and amniotic fluid (Roberts et al, 1995; Aidan et al, 1999). Thus, in order to clearly distinguish these middle ear problems from sensorineural hearing loss, a brief, accurate, and noninvasive middle ear diagnostic tool would be a useful adjunct to OAE screening.

An alternative tool to assess middle ear function is known by various terms, including wideband middle ear impedance (Allen, 1986), wideband reflectance (Keefe, 1992), and wideband middle ear power or WMEP measurement (Allen et al, 2005). This technique uses a broad range of frequencies—from 62 Hz to 13,000 Hz depending on the equipment and calibration method. *WMEP* is a broad term that includes power reflectance as well as admittance and impedance quantities and has the potential to increase the accuracy of diagnosing middle ear pathologies in infants failing newborn screening (Keefe et al, 2003). WMEP is a physiological measure of the middle ear that uses a broadband frequency stimulus and analysis method to provide detailed information about middle ear properties, particularly across the frequency range most important for speech perception (Keefe et al, 1993; Keefe and Levi, 1996).

WMEP requires a sensitive calibration system to measure power reflectance, or the sound energy not absorbed by the middle ear after a sound is presented into the ear (Voss and Allen, 1994). Power reflectance is measured as a proportion of the presented sound stimulus, ranging from 0.0 to 1.0. It is also possible to obtain responses for a range of air pressure settings as in standard tympanometry (Margolis et al, 1999). Power reflectance is one of several acoustic variables that can be measured using WMEP. Allen, Jeng, and Levitt (2005) describe the derivation and clinical significance of these related variables, including power absorption, transmittance or power absorption in decibels, acoustic impedance (resistance and reactance), and admittance (conductance and susceptance).

Few normative data for WMEP have been reported, and data on clinical effectiveness and reliability are also needed. At all ages, power reflectance is highest at frequencies below 1000 Hz and above 4000 Hz and lowest in the frequency region between 1000 and 4000 Hz, which corresponds to the most effective frequency region of the middle ear transfer function (Keefe et al, 1993). Infants have lower reflectance at low frequencies compared to adults but similar reflectance at high frequencies (Keefe et al, 1993). This could be due to power loss from flaccid canal wall motion apparent in newborn infants. Canal wall motion is not significant for the frequency region of 2000–4000 Hz, and high reflectance in the range of 2000–4000 Hz has been reported to occur with middle ear dysfunction (Keefe et al, 2003). Feeney and Sanford (2005) measured wideband reflectance and impedance in three adults and five infants aged six weeks using the experimental system developed by Keefe. They also report that significantly higher impedance and significantly lower reflectance were found at all frequencies for the infants compared to adults, and the difference was greatest in the low-frequency region.

Aging effects also have been reported. Feeney and Sanford (2004) report wideband reflectance measures in 40 young adults and 30 older adults (≥60 years). Significant age-related effects were present with a decrease in reflectance from 80 to 2000 Hz and an increase near 4000 Hz. These effects were thought to be due to decreased middle ear stiffness with age.

It is possible to measure WMEP using either broadband chirp or frequency-specific (sine wave) stimuli. The primary advantage to using sine wave stimuli is the potential to control the signal-to-noise ratio (SNR) of the response within the specific frequency range of interest, similar to signal-to-noise algorithms that have been applied in distortion product otoacoustic emission (DPOAE) measurements. In infants, noisy responses may be obtained, particularly below 1000 Hz. The SNR for digital signals, such as those measured by WMEP, is the energy in the signal per bit of information carried by the signal, relative to the amount of noise power per hertz of signal bandwidth (the noise power spectral density), or E_b/N_0. For a sine wave stimulus, the noise power contained within the spectral bandwidth of measurement is much lower than it is for a broadband signal, such as a chirp stimulus. Improvements in the SNR on the order of 50 dB can be achieved by using the sine wave stimulus compared to the broadband chirp stimulus (J. Allen, personal communication, 2006). Thus, use of a sine wave stimulus should improve ability to manage background noise and obtain a better SNR in the response.

In this study, we obtained normative data for several immittance components using WMEP, including wideband reflectance, absorption, transmittance, impedance, and admittance for infants and children from birth to four years old. This study was designed to address the following research questions using a prototype commercial instrument:

1. Are significant differences present in wideband middle ear measures based on age from birth to 47 months?

2. Are significant differences present in wideband middle ear measures based on gender, ear (right vs left), or middle ear status?

3. Are wideband middle ear measures reliable in infants and toddlers?

4. Are equivalent results obtained for broadband chirp and sine wave stimuli?

METHOD

Infants and children enrolled in the study were patients at the University of Utah Hospital Pediatric Clinic. Parents were informed of the study and given the opportunity to enroll their child while attending a regularly scheduled well-child visit. An Institutional Review Board–approved consent form was used to obtain parent permission. Children enrolled in the study first received otoscopic examination by their pediatrician. Using a study ear examination form, the physician rated mobility, color, and position of the tympanic membrane, as well as the presence of middle ear effusion when apparent. The investigators did not have access to otoscopy results prior to testing, and physicians did not have access to WMEP, OAE, or tympanometry results until all testing had been completed. Parents were questioned regarding OME history as well as factors known to be associated with congenital hearing loss (family history of hearing loss, craniofacial anomaly, birth weight below 1500 g, low Apgar scores, syndromes associated with hearing loss, ototoxic medications for greater than five days, mechanical ventilation for greater than five days, and congenital infections [Joint Committee on Infant Hearing, 2000]). Subject state (i.e., sleeping, awake, fussy, crying) during testing was also recorded. One child was excluded due to cleft lip and palate, and two children were excluded due to recent diagnosis of OME, including one child with tympanostomy tubes.

Ninety-seven subjects (194 ears), including 51 males and 46 females, ranging in age from three days to 47 months were enrolled in the study. Subjects were separated into groups according to age. Age and gender distributions are shown in Table 1.

Procedures

DPOAEs, WMEP, and tympanometry were completed for both ears of each child. WMEP was tested twice using broadband chirps and once using sine waves for analysis of test–retest reliability. The probe tip was removed and reinserted prior to the second chirp test. All testing was performed in an examination room with the door closed to reduce ambient noise. The most accessible ear was tested first. Test order of DPOAE and WMEP was alternated between subjects. Tympanometry was tested last because the pressure used in tympanometry can sometimes cause the child to become fussy. Testing was initially attempted without nursing or the use of bottles or pacifiers. If the child could not be calmed in other ways, then nursing, bottle-feeding, or a pacifier was allowed. Testing was performed once the child was as quiet as possible.

DPOAE testing was conducted using a Mimosa Acoustics, Inc. (Champaign, Ill.), DPOAE instrument. In situ calibration was completed for each ear of every subject. The relative f_2 to f_1 frequency ratio was 1.22, and the intensity level of the primary tones was set at 65 and 55 dB SPL (in situ tolerance ±5 dB) during testing at each frequency, where f_1 was the higher-level tone. DPOAEs were examined for signal-to-noise ratio and absolute signal level at f_2 primary frequencies of 2000–6000 Hz. Passing criteria was an SNR of 6 dB or more for three of four frequency bands between 2000 and 6000 Hz (Gorga et al, 2000).

WMEP was measured using the Mimosa RMS-IV measurement system (Mimosa Acoustics RMS System), which consists of a laptop computer, a PC digital signal processor board, an ER-10C probe (Etymotic Research, Elk Grove Village, Ill.), and a specialized calibration cavity set (CC4-V). The same silicone or foam tip used in DPOAE was used for WMEP. Reflectance measurements depend on the cross-sectional area of the ear canal in the plane of measurement (S), as noted in Equation 1 below. Different reflectance measurement systems may estimate S acoustically or physically. The Mimosa system estimates S physically, based on the diameter of the ear tip used for the measurement. For the present study, three different tip sizes were used: ER10C-04 (4.5 mm), ER10C-05 (5.5 mm), and ER10C-14B (child foam tip, 14 mm). The largest tip that provided a snug seal in the ear canal was selected to avoid acoustic leaks.

Calibration of the chirp stimulus using an analysis of time delay and frequency response was performed in a series of four hard-wall cavities of selected lengths (CC4-V cavity set) designed and described by Voss and Allen (1994). The Thévenin equivalent parameters, source pressure, and impedance were measured first in the calibration cavities and then in the ear using the same-size probe tip. For further calibration and instrumentation details, refer to Voss and Allen (1994). Unlike with tympanometry, pressure within the outer ear canal was not varied in the WMEP measures for this study. Thus, all WMEP measurements represented middle ear function at ambient pressure.

Digitally synthesized chirps at 55 dB SPL were then presented through the tip into the ear canal. The stimulus intensity was increased up to 65 dB SPL as necessary to ensure that the stimulus in the ear canal was above the noise floor. Pressure frequency response and power reflectance were computed by the software program from Thévenin equivalent parameters obtained during calibration. A minimum of 50 chirps and up to 200 chirps at a rate of 12.5 chirps/sec were presented and averaged. More averages were acquired, and the test was repeated if excessive noise was apparent in the first waveform. Parameters analyzed included the percentage of power reflectance, which is the square of pressure reflectance, across the range of frequencies from 258 to 6000 Hz, or the proportion of

Table 1. Age and Gender Distribution of Subjects Enrolled in the Study

Age Range	Male	Female	Total
3 days to 2 months	11	7	18
3 to 5 months	11	4	15
6 to 11 months	10	15	25
12 to 23 months	10	10	20
24 to 47 months	9	10	19
Total	51	46	97

retrograde-to-incident power reflected by the middle ear and cochlea, given by

Power reflectance = $|R(f)|^2$
(Eq. 1)

where R(f) = (Zec[f] – Z0) / (Zec[f] + Z0); Z0 = rho*c/S; and rho is the density of air, c is the speed of sound, and S is the cross-sectional area of the ear canal in the plane of measurement.

A second variable derived from power reflectance is power absorption, which is 1 – power reflectance, given by

Power absorption = $1 - |R(f)|^2$
(Eq. 2)

A third variable derived is transmittance, which is absorbed power transformed to a logarithmic scale in decibels:

Power transmittance = $10\log_{10}(1 - |R[f]|^2)$
(Eq. 3)

As noted by Allen and colleagues (2005), transmittance is a conceptually straightforward measure because the use of the decibel scale simplifies comparison with other data, such as hearing thresholds and OAE response levels.

A GSI Tympstar multifrequency acoustic immittance instrument (Grason Stadler, Inc., Madison) was used to obtain tympanometry. Volume calibration was performed for

Table 2. Tympanometry Results for Normal Compared to Poor Ear Status

Variable	Ear Status	N	Mean	Standard Deviation	P Value
Y1000	Normal	129	2.49	1.99	
	Poor	19	0.36	0.69	< .001
Y226	Normal	138	0.52	0.31	
	Poor	21	0.03	0.08	< .001

Note: Numbers represent ears and vary due to missing data for various reasons such as lack of cooperation or excessive artifact in the recordings.

Table 3. Energy Reflectance, R_2, for Normal- Compared to Poor-Status Ears for the Chirp Stimulus at Selected Frequencies

Frequency (Hz)	Mean R_2 (%), Normal Status (N = 138)	Mean R_2 (%), Poor Status (N = 21)	Standard Deviation for R_2 (%), Normal Status (N = 138)	Standard Deviation for R_2 (%), Poor Status (N = 21)	P Value
258	86.08	94.05	20.231	12.272	.098
492	74.81	82.21	22.905	20.660	.188
750	56.91	67.53	24.447	26.651	.085
1008	47.74	72.89	24.296	20.981	.000*
1500	35.01	57.89	22.212	29.006	.000*
1992	26.47	52.68	21.081	28.420	.000*
3000	23.45	44.53	17.421	26.220	.000*
4008	26.23	42.58	22.630	28.731	.006*
6000	45.88	67.63	27.368	33.019	.002*

Note: *p-value was significant at the .05 level. Mean, standard deviation, and p value for post hoc tests, corrected by Bonferroni adjustment from a repeated-measures analysis of variance are shown.

tympanometry daily. Both a 226 Hz probe tone and a 1000 Hz probe tone were used for tympanometry. Pressure was changed from the positive to negative direction and varied from +200 daPa to –400 daPa. The pressure rate of change was 600 daPa/sec at the extreme pressure ranges and 200 daPa/sec near the peak of the tympanogram. Susceptance (B) and conductance (G) tympanograms were obtained at both probe frequencies. In infants under six months, tympanograms were acquired first using a 1000 Hz probe tone followed by a 226 Hz probe tone, and the reverse order was tested in older children. Peak compensated static acoustic admittance (Y_{tm}) was derived from the peak compensated susceptance (B_{tm}) and peak compensated conductance (G_{tm}) values using the following equation:

$$Y_{tm} = \sqrt{B_{tm}^2 + G_{tm}^2}$$
(Eq. 4)

where $B_{tm} = B_{peak} - B_{tail}$ and $G_{tm} = G_{peak} - G_{tail}$.

Values for tympanometric peak pressure, tympanometric width at 50 percent of Y_{tm} (226 Hz only), and equivalent ear canal volume were also measured. However, since tympanometric width cannot be measured when notching is present in the susceptance or conductance tympanograms, it was not used for pass/fail criteria for this study. Passing criteria for the purpose of this study for Y_{tm} were >0.2 mmho or >0.6 mmho for the 226 Hz and 1000 Hz probe tone frequencies, respectively. These values were chosen based on studies by Roush, Bryant, Mundy, Zeisel, and Roberts (1995) and Palmu, Puhakka, Huhtala, Takala, and Kilpi (2001) for 226 Hz. For 1000 Hz, a cutoff criterion of 0.6 mmho as recommended by Margolis, Bass-Ringdahl, Hanks, Holte, and Zapala (2003) was used.

Algorithm for Ear Status Determination

In this study, three tests (otoscopy, tympanometry at either 226 or 1000 Hz, and DPOAE) were used to determine ear status in an algorithm. At least two of the three tests had to have complete data in order to apply the algorithm. If two tests were in agreement as being abnormal or normal, the ear was classified accordingly. In the event of a tie (e.g., only two tests were completed and one of two was abnormal), then tympanometry was given stronger weight than either otoscopy or DPOAE. If only otoscopy and DPOAE were available (this was the case in only two ears), then otoscopy was given stronger weight, for DPOAE could have failed due to an undetected sensorineural hearing loss. Ears that were classified as normal by the algorithm were called "normal-status ears." Ears that were classified by the algorithm as abnormal were called "poor-status ears." Additionally, there were several ears that passed the algorithm but had significant negative or positive tympanometric peak pressure (TPP). The effect of TPP on reflectance was analyzed separately for these ears.

Statistical Analysis

SPSS Version 7.0 was used to analyze data. Repeated-measures analysis of variance (ANOVA) was used to compare chirp and sine wave stimuli, age group, ear status, and gender. In all ANOVA analyses, stimulus frequency was the repeated factor, and the other variables (stimulus type, age, ear status, and gender) were used as the grouping factors. When the overall ANOVA was significant, post hoc tests were performed with Bonferroni correction. Intraclass correlation coefficients were calculated at nine test frequencies to examine test–retest reliability. This statistic was chosen because the pairs of observations do not have an obvious order (Shrout and Fleiss, 1979). A significance level of $p \leq .05$ was used for all analyses.

RESULTS

Ear status was determined by the combined test algorithm of otoscopy, tympanometry, and DPOAE. A total of 159 ears of 81 children had complete tests available for the algorithm to be applied. Individual tests were missing for various reasons such as lack of cooperation by the child, inadequate signal level for OAE testing, ear blockage (wax), poor probe seal, or artifact in the recordings. Twenty-one ears were classified as having poor ear status by the algorithm, whereas 138 ears were classified as having normal ear status. Seven of the poor-status ears were in infants less than six months old, and 14 were in infants older than six months. Y_{tm} was compared for normal- and poor-status ears for both 226 and 1000 Hz probe tones. Table 2 provides mean, standard

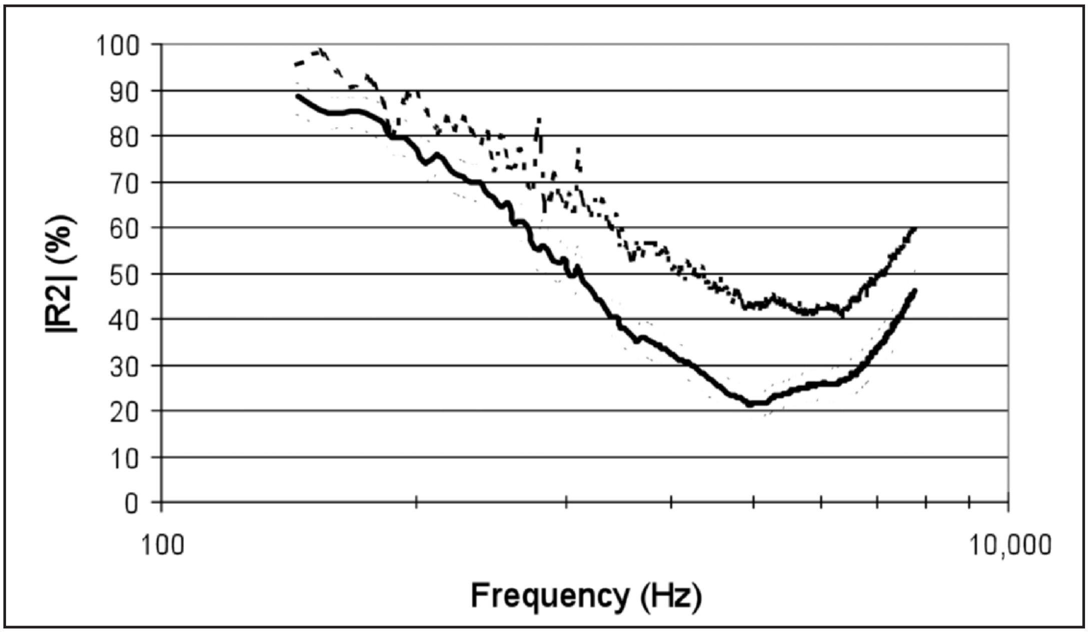

Figure 1. Average power reflectance (chirp stimulus) for ears with normal ear status (n = 138) shown with the solid line; 95 percent confidence intervals are shown with dotted lines. Comparison group is ears with poor status (n = 21; dashed line).

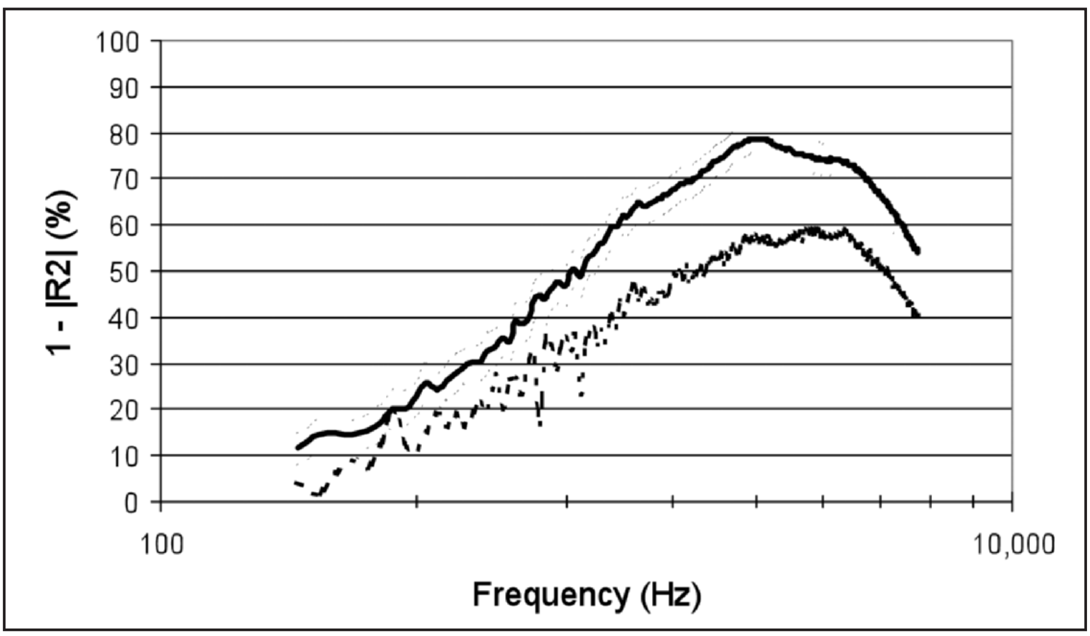

Figure 2. Average power absorption (chirp stimulus) for ears with normal ear status (n = 138) shown with the solid line; 95 percent confidence intervals are shown with dotted lines. Comparison group is ears with poor status (n = 21; dashed line).

deviation, and p-values for t-tests. Y_{tm} was significantly lower in the ears with poor status for both the 226 Hz and 1000 Hz probe tones, consistent with a diagnosis of otitis media in the poor-status ears.

Repeated-measures ANOVAs were used to investigate effects of ear status on measures of WMEP using stimulus frequency as the repeated factor and ear status as the grouping factor. Power reflectance was significantly higher in the ears with poor ear status (overall ANOVA $p < .001$), and post hoc tests with Bonferroni correction revealed that frequencies between 1008 and 3000 Hz were significantly different for normal compared to poor ear status (Table 3). Figure 1 shows the effect of ear status on power reflectance as a function of stimulus

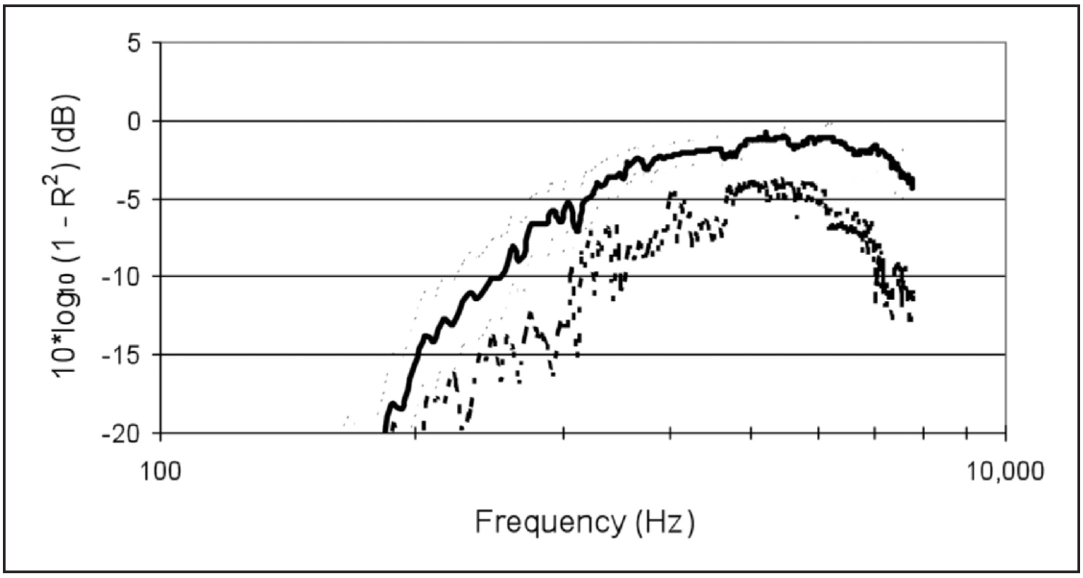

Figure 3. Average transmittance (chirp stimulus) for ears with normal ear status (n = 138) shown with the solid line; 95 percent confidence intervals are shown with dotted lines. Comparison group is ears with poor status (n = 21; dashed line).

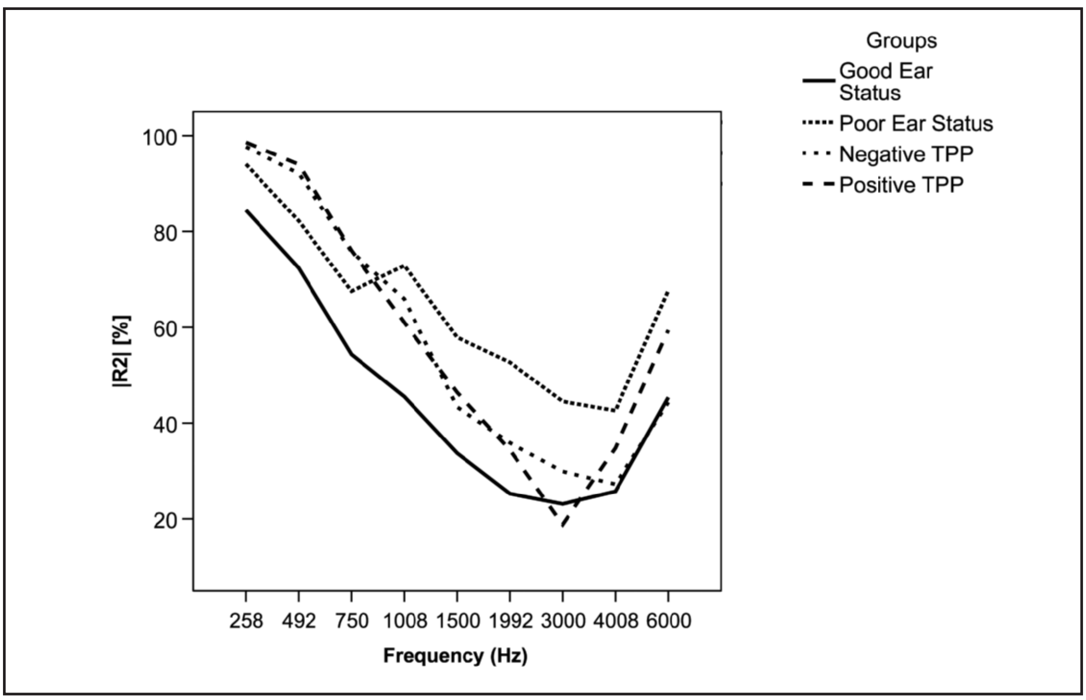

Figure 4. Average power reflectance for ears with normal status (n = 124) compared to ears with poor status (n = 21), ears with tympanometric peak pressure (TPP) <–100 daPa (n = 9), and ears with TPP >100 daPa (n = 5).

frequency. Likewise, ears with poor status showed lower power absorption (Figure 2) and lower transmittance (Figure 3). The effect of tympanometric peak pressure was investigated by comparing ears with normal TPP (between –99 and +99 daPa), those with negative pressure (≤–100 daPa), those with positive pressure (≥100 daPa), and those with poor ear status. As shown in Figure 4, reflectance appeared to be increased in frequency regions below 2000 Hz with both positive and negative TPP but was statistically insignificant at all frequencies, probably due to the small number of ears with positive or negative pressure. Although statistically insignificant, ears with positive or negative TPP were excluded from the remaining analysis for age, gender, and ear.

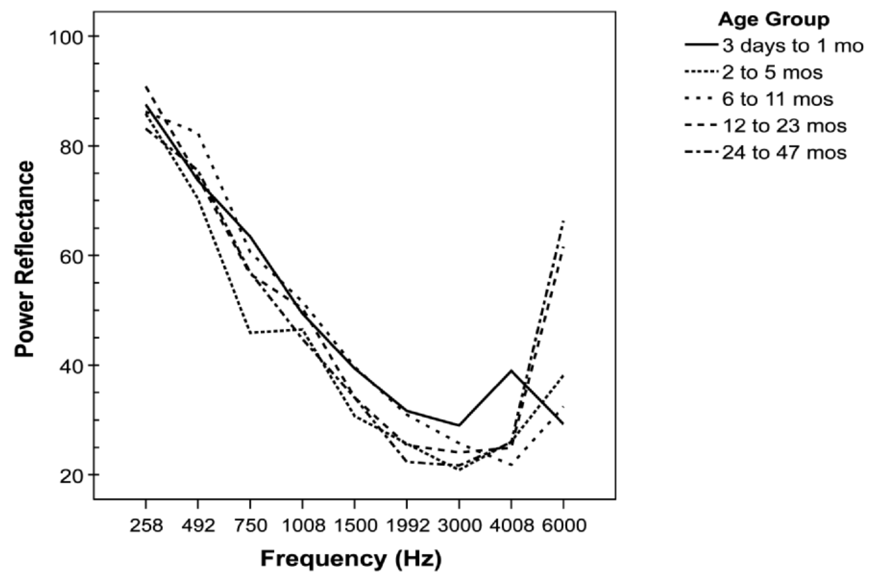

Figure 5. Average power reflectance (chirp stimulus), with 95 percent confidence intervals for normal-status ears, separated into age groups.

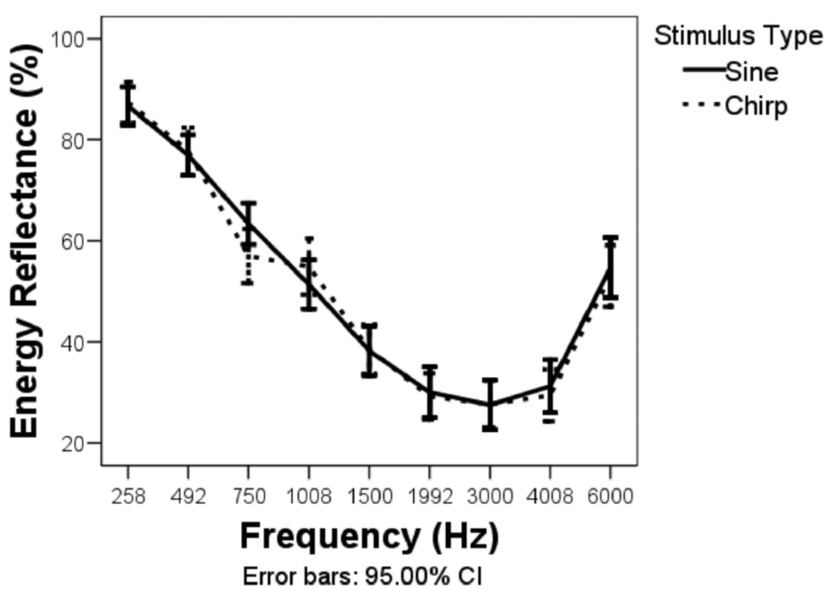

Figure 6. Average power reflectance for broadband chirp compared to sine wave stimuli for all ears with normal status in which both stimulus types were completed (n = 93). Error bars are 95 percent confidence intervals.

Repeated-measures ANOVA was used to investigate effects of age group for normal-status ears, using stimulus frequency as the repeated factor and age group as the between factor. The ANOVA was done using all ears (both ears when normal), as well as only the right ear (or the left if the right was abnormal or unavailable). No significant differences were found in the overall ANOVA for reflectance as a function of age group ($p = .373$ when both ears were included; $p = .546$ when limited to one ear per subject). Average power reflectance across different age groups from 0 to 47 months (using data from both ears) is shown in Figure 5. Although some variability occurred across age groups, there was no apparent systematic effect, and the 95 percent confidence intervals overlapped from birth to four years of age. In order to determine if our subject pool, which was distributed across a continuum, may have contributed to a lack of statistical significance for the ANOVA test, we also tested for an age effect using Pearson product–moment correlations at each frequency. The only stimulus frequency that showed a significant correlation with age was 6000 Hz, which had a positive correlation of r = 0.55 with age ($p < .001$). The other correlations were all low and nonsignificant.

A repeated-measures ANOVA was used to investigate effects of gender and ear (right vs left), using stimulus frequency as the repeated factor and gender or age as the grouping factor. No significant differences were found in the overall ANOVA for male/female gender ($p = .932$) or right/left ear ($p = .199$).

Ears classified as normal status were selected to investigate effects of stimulus type (chirp and sine wave). Figure 6 plots power reflectance as a function of frequency and shows that there was a systematic effect across stimulus frequency for both chirp and sine wave stimuli, with highest reflectance found for low frequencies (258–750 Hz), lowest reflectance for mid frequencies (1500–4000 Hz), and rising again to high reflectance values at 6000 Hz and above. Repeated-measures ANOVA was significant, as expected, for changes in power reflectance across frequencies ($p < .001$). No significant difference was found between chirp and sine wave stimuli ($p = .837$), indicating that power reflectance was not significantly different for the two stimulus types.

The reliability of wideband reflectance was investigated with intraclass correlation coefficients (ICCs). Table 4 shows ICCs for test versus retest across frequencies. ICC was significant and high across all frequencies, indicating good reliability (Shrout and Fleiss, 1979).

Normative values for wideband reflectance are provided in Table 5 for ears that were classified as normal by the algorithm, with the exclusion of ears that had measured TPP of >100 daPa or <–100 daPa (significant positive or negative TPP). Although we found age-related effects only at 6000 Hz for WMEP, normative data are provided for infants less than six months separately from data for those six months and older due to previous reports of age-related changes. As no significant effects of gender or ear were found, values were collapsed across gender and ears.

DISCUSSION

Strengths of the current study include a broad range of age from birth to 47 months because this age range is of greatest interest for the diagnosis of otitis media with effusion. This study employed three physiological tests including hearing screening with DPOAE, tympanometry at 226 or 1000 Hz, and wideband middle ear power measurement to exclude ears with otitis media. In addition, children were examined by their pediatricians with otoscopy. A clinical algorithm was used to determine ear status so that the determination of normal ear status was rigorous. Children were tested in an environment that is generalizable to typical medical clinics. The study population was also relatively generalizable, with an equal proportion of males and females and an ethnic mix that included children of Caucasian, Asian, Hispanic, African American, and Pacific Islander backgrounds. Although ethnicity was not specifically tracked for the purposes of the study, approximately 25 percent of children were non-Caucasian.

In order to use WMEP as a clinical tool, additional information is needed regarding

Table 4. Intraclass Correlation Coefficients for Chirp Stimuli for Test vs Retest after Removal and Reinsertion of the Probe Tip

Frequency (Hz)	Intraclass Correlation Coefficient
258	0.965
492	0.828
750	0.856
1008	0.878
1500	0.784
1992	0.679
3000	0.701
4000	0.831
6000	0.888

Table 5. Normative Data for Wideband Reflectance for Chirp Stimuli at Selected Frequencies for Infants Less Than Six Months and 6–47 Months

Frequency (Hz) by Infant Age	Average Reflectance	Standard Deviation	5th Percentile	95th Percentile
3 days to 5 months				
258	82	26	28	100
492	66	27	22	100
750	53	27	13	100
1008	46	26	12	98
1500	32	23	5	78
1992	25	18	7	56
3000	25	17	4	59
4008	33	24	4	72
6000	35	23	4	75
6–47 months				
258	87	17	53	100
492	78	21	44	100
750	61	26	23	100
1008	49	24	17	100
1500	37	22	7	76
1992	26	21	4	64
3000	23	18	2	58
4008	21	19	1	59
6000	54	27	7	100

Note: Ears with poor status or negative or positive tympanometric peak pressure were excluded.

effects of age to determine if different normative values will be required. The present study did not find a significant age effect within the frequency range tested, except at 6000 Hz. In contrast, Keefe and colleagues (1993) report a significant effect of age from birth to adult age ranges, with the largest change found from birth to six months of age. In the Keefe and colleagues study, the largest age effects were found below 1000 Hz, with an increase in reflectance from birth to about six months of age. Figure 7 provides a comparison of the age effects reported by Keefe and colleagues (1993) and similar ages in the present study. Keefe and colleagues report that effects were smaller in the mid-frequency region, consistent with the current study. Data from the Keefe and colleagues and the present study were quite similar between 1000 and 6000 Hz. In the youngest age group studied by Keefe and colleagues, reflectance was lower from 250 to 750 Hz than for the youngest age group in the present study. The number of subjects in the Keefe and colleagues study between birth and age two years was 78 (10–23 per age grouping); the present study included 97 subjects distributed from birth through age three years. Thus insufficient sample size does not appear to explain the lack of an age effect in the current study. Potentially important differences among Keefe and colleagues (1993), Feeney and Sanford (2005), and the present study include the probe design and calibration method.

An important factor that could affect reflectance measures, especially for infants and children, is the rapid developmental increase in the cross-sectional area of the ear canal. In the system developed by Keefe and colleagues (1993), the cross-sectional area of the ear canal is calculated based on the measured impedance. The Mimosa system estimates S physically, based on the diameter of the ear tip used for the measurement. For the present study, three different tip sizes were used—4.5 mm, 5.5 mm, and 14 mm—depending on which provided a snug seal to avoid acoustic leaks. As the tip must be large enough to ensure a good seal in the ear canal, then the tip size is likely to be the same as or slightly larger than the ear canal cross section. Therefore, the resulting R(f) measurement could be overestimated if the tip size is larger than the ear canal. For infants, errors due to differences between the tip size and the actual ear canal size would be expected to be smaller than in older children because rubber tips were used, and the rubber tips cannot be compressed as much as foam tips, which were used in older children. Thus, this explanation does not appear to explain the relatively higher reflectance seen in low frequencies for the youngest group in our study compared to the results in studies by Keefe and colleagues (1993) and Feeney and Sanford (2005).

Another factor that may affect reflectance measurements is the seal within the ear canal and the depth of probe tip insertion. As noted by Keefe and colleagues (2000) and Feeney and Sanford (2005), a poor probe tip seal allows loss of energy in the low-frequency portion of the stimulus and decreases reflectance measured in the ear canal. This effect occurs primarily in the low frequencies, as shown in Figure 8. Thus, depth and tightness of the probe tip can have a large effect on reflectance in the low frequencies. In the present study, if reflectance in the low frequencies appeared to signify a leak, indicated by reflectance below 0.3 in the low frequencies, excessive noise, or variability upon retest, then the next larger tip was used, and the measurement was repeated. Once the testers became familiar with the system and learned techniques for good probe fit, the need to refit probes due to leaks was rare. For these reasons, this study should be free of error due to poor probe tip fit.

The depth of insertion could also have an effect due to compliance of the ear canal in the cartilaginous portion, which is highly compliant in newborns. The design of the rubber tip we used tapers at the distal portion of the tip. To obtain a good seal, these tips must be inserted at least 3–4 mm into the ear canal, which may be past the most compliant portion of the ear canal. Deeper tip insertion could be an explanation for the relatively higher measured reflectance in the low frequencies in the present study compared to the findings of Keefe and colleagues (1993).

The lack of a significant age effect using the Mimosa Acoustics system simplifies the development of normative standards and could enhance the feasibility of using wideband middle ear power measurement for assessment of newborn middle ear status. However, these findings need to be replicated with the

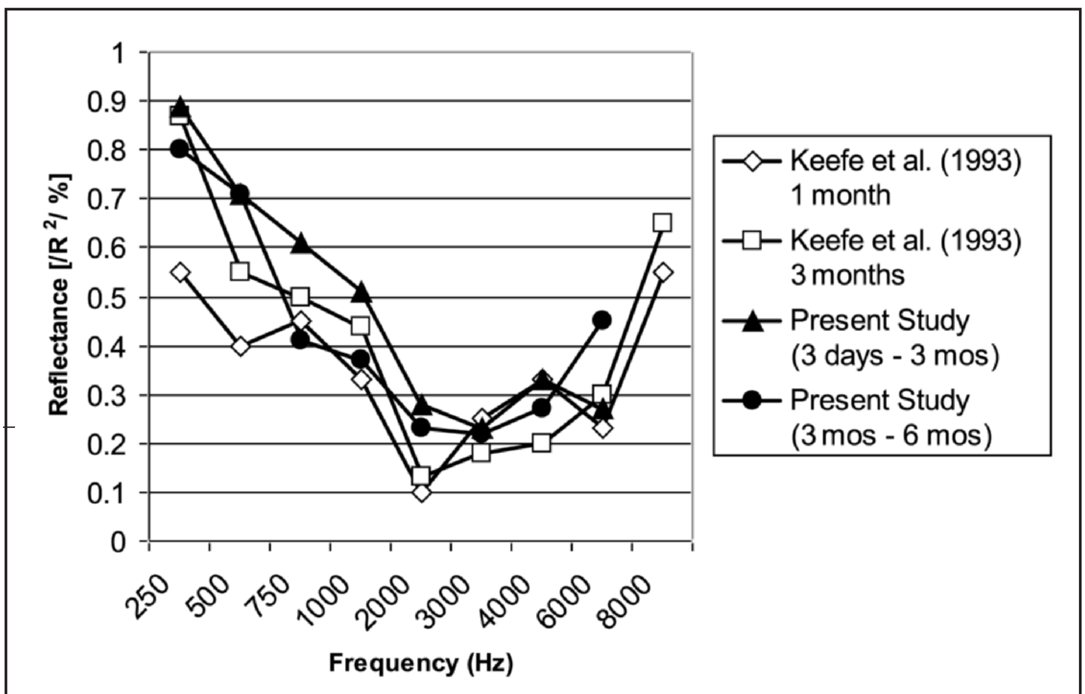

Figure 7. Wideband power reflectance for the present study and for a previous study in normal infants.

Mimosa and other systems that may be developed. We found no significant effects of ear or gender for power reflectance, indicating that normative data may be collapsed across ears and for males and females.

Previous comparative studies of different stimuli for the measurement of power reflectance are not available. The issue of stimulus type is important, for there could be advantages to using sine wave stimuli, in that use of specific test frequencies allows more control over signal-to-noise ratio, an important consideration in testing in higher background noise, such as in newborns and infants. Additionally, if certain frequency regions are identified as having optimal diagnostic sensitivity and specificity, testing could focus on the optimal frequency region, saving time and simplifying analysis. The results of this study demonstrate that broadband chirp and specific sine wave stimuli were equivalent for measures of power reflectance. The equivalence of broadband and sine wave test stimuli indicates that either stimulus type could potentially be used for measurement, but more research is needed about the diagnostic efficiency of these different stimulus types and the conditions under which there may be advantages and disadvantages of each type.

Few data are currently available concerning the effects of otitis media in young children on power reflectance and its associated measures. The results of this study demonstrate a significant difference in middle ear reflectance, absorption, and transmittance characteristics in ears clinically defined as having poor ear status (i.e., otitis media with effusion), in the frequency range of 1000–4000 Hz. Small differences were also observed with increased or decreased TPP, primarily below 1000 Hz. Margolis, Paul, Saly, and Schachern (2001) also demonstrate differences in reflectance due to increased or decreased pressure produced within the ear canal experimentally.

A potential limitation of WMEP measures appears to be normal variability. As with static admittance measures, normal variability of the middle ear is quite high, as shown by the 5th to 95th percentiles for normal ears in Table 5 and the degree of overlap between normal- and poor-status ears in Table 3. Thus, validation studies that determine sensitivity and specificity are needed to determine test effectiveness and which measurement parameters are optimal for clinical use.

No previous data were found in the literature concerning the test–retest reliability of wideband middle ear power measures. This study found high intraclass correlation values, indicating substantial reliability of repeat measures within the same test session, even after removal and reinsertion of the probe tip. Sources of measurement variance include the insertion depth and seal of the probe tip, internal noise in the ear canal, external noise in the test room, and calibration of the probe. All of these factors, except probe calibration, could vary from one test to the next within the same session. Differences from one test session to another, outside the boundaries of what was found in the present study, would be expected to be related to actual changes in the status of the ear. One consideration affecting generalizability for the current study is that the ICC is strongly influenced by the variance of the trait in the sample/population in which it is assessed. In this population, otitis media occurred in a small proportion of otherwise

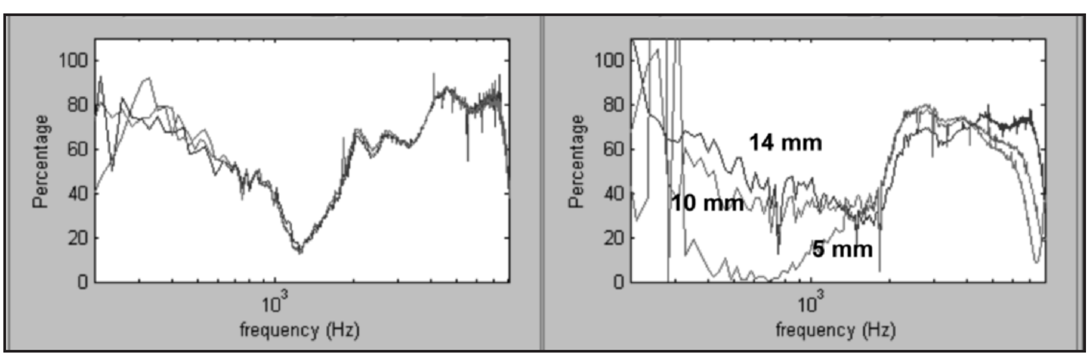

Figure 8. Effect of test–retest measures and probe insertion depth. Left panel: Power reflectance with three consecutive tests after probe removal and reinsertion to the same depth each time. Right panel: Power reflectance with three consecutive tests after probe removal and reinsertion to 14, 10, and 5 mm depths, respectively.

healthy children (15% of ears), consistent with previous studies of OME rates in otherwise healthy young children. Thus, the ICC may have been influenced by the normality of the population. Reliability should also be assessed in future studies in other populations, such as children with otitis media and newborns receiving hearing screening, as ICCs measured for different populations might not be comparable. In conclusion, this study found that WMEP measurements had good test–retest reliability; power reflectance was significantly higher in ears with otitis media; no significant age effects were found from birth through three years of age except at 6000 Hz; no significant gender or ear effects were found; and results were equivalent for broadband chirps and specific sine wave stimuli.

Acknowledgments. We thank Patricia Jeng, Harry Levitt, Jont Allen, Pat Feeney, and an anonymous reviewer for their comments and suggestions. For their support of the study, we also thank the participating families; Cheryl Henderson, Charles Norlin, Katie McElligott, Lisa Sampson-Fang, and Bruce Herman; as well as the nurses and staff of the University of Utah Pediatric Clinic.

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