Reflectance Measures from Infant Ears With Normal Hearing and Transient Conductive Hearing Loss

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Objective: The objective is to develop methods to utilize newborn reflectance measures for the identification of middle-ear transient conditions (e.g., middle-ear fluid) during the newborn period and ultimately during the first few months of life. Transient middle-ear conditions are a suspected source of failure to pass a newborn hearing screening. The ability to identify a conductive loss during the screening procedure could enable the referred ear to be either (1) cleared of a middle-ear condition and recommended for more extensive hearing assessment as soon as possible, or (2) suspected of a transient middle-ear condition, and if desired, be rescreened before more extensive hearing assessment.

Design: Reflectance measurements are reported from full-term, healthy, newborn babies in which one ear referred and one ear passed an initial auditory brainstem response newborn hearing screening and a subsequent distortion product otoacoustic emission screening on the same day. These same subjects returned for a detailed follow-up evaluation at age 1 month (range 14 to 35 days). In total, measurements were made on 30 subjects who had a unilateral refer near birth (during their first 2 days of life) and bilateral normal hearing at follow-up (about 1 month old). Three specific comparisons were made: (1) Association of ear's state with power reflectance near birth (referred versus passed ear), (2) Changes in power reflectance of normal ears between newborn and 1 month old (maturation effects), and (3) Association of ear's newborn state (referred versus passed) with ear's power reflectance at 1 month. In addition to these measurements, a set of preliminary data selection criteria were developed to ensure that analyzed data were not corrupted by acoustic leaks and other measurement problems.

Results: Within 2 days of birth, the power reflectance measured in newborn ears with transient middle-ear conditions (referred newborn hearing screening and passed hearing assessment at age 1 month) was significantly greater than power reflectance on newborn ears that passed the newborn hearing screening across all frequencies (500 to 6000 Hz). Changes in power reflectance in normal ears from newborn to 1 month appear in approximately the 2000 to 5000 Hz range but are not present at other frequencies. The power reflectance at age 1 month does not depend significantly on the ear's state near birth (refer or pass hearing screening) for frequencies above 700 Hz; there might be small differences at lower frequencies.

Conclusions: Power reflectance measurements are significantly different for ears that pass newborn hearing screening and ears that refer with middle-ear transient conditions. At age 1 month, about 90% of ears that referred at birth passed an auditory brainstem response hearing evaluation; within these ears the power reflectance at 1 month did not differ between the ear that initially referred at birth and the ear that passed the hearing screening at birth for frequencies above 700 Hz. This study also proposes a preliminary set of criteria for determining when reflectance measures on young babies are corrupted by acoustic leaks, probes against the ear canal, or other measurement problems. Specifically proposed are "data selection criteria" that depend on the power reflectance, impedance magnitude, and impedance angle. Additional data collected in the future are needed to improve and test these proposed criteria.

Key words: Immittance, Middle ear, Newborn hearing screening, Otitis media, Reflectance.

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INTRODUCTION

Hearing loss affects one to three of every 1000 newborns, making it among the most common birth defects. The American Academy of Pediatrics advocates universal newborn hearing screening because undetected hearing loss has been shown to compromise cognitive, speech, and language development (Joint Committee on Infant Hearing 2007). As of 2005, every state had a newborn hearing screening program in place, and as of 2012, 98% of newborns are screened for hearing loss (Centers for Disease Control and Prevention 2013).

Hearing screening is not designed to identify the cause or degree of hearing loss at the time of birth, but to identify those babies who should be tested in greater detail to determine hearing status. Some ears refer at the newborn hearing screening due to permanent hearing loss, whereas others refer due to transient conditions of the external or middle ears that may clear within the first few days or weeks of life (e.g., vernix or other debris in the ear canal or fluid in the middle ear). It has been estimated that approximately 90% of newborn ears that do not pass their hearing screening refer as a result of transient conditions and are later found to have normal hearing (Thompson et al. 2001). Sanford et al. (2009) found that 79% of 67 newborn ears that did not pass a newborn hearing screening distortion product otoacoustic emissions (DPOAE) test passed the same test 1 day later, suggesting that their referrals were caused by ear conditions that cleared by the second day of life. In a study examining the effects of outer and middle ear conditions on newborn hearing screening results, Doyle et al. (2000) observed reduced tympanic membrane mobility, suggestive of middle ear fluid, in 90 of 396 newborn ears.

The prevalence of transient middle ear conditions at the time of newborn hearing screening suggests the need for tools that provide more complete information about ear status during the newborn period and in the early months of life (Joint Committee on Infant Hearing 2007). Because infants with middle ear fluid are more likely to develop otitis media with effusion by the age of one (Doyle et al. 2004), a tool for identifying transient middle ear conditions in newborns would also help identify infants at risk for later chronic otitis media with effusion. The detection of transient middle ear conditions in the first months of life can be difficult because 226 Hz tympanometry is not reliable in ears younger than 4 to 6 months old (e.g., Holte et al. 1991).

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Recently, both reflectance measures and 1000 Hz tympanometry have been proposed as potential methods to detect transient middle ear conditions near the time of birth, with Sanford et al. (2009) and Hunter et al. (2010) finding that reflectance measures outperform 1000 Hz tympanometry at predicting DPOAE screening results near birth. Merchant et al. (2010) and Hunter et al. provide substantial background material and literature reviews regarding the role of reflectance measures to help identify transient middle ear conditions during the newborn period.

This present study reports reflectance measures on the ears of babies who underwent universal auditory brainstem response (ABR) newborn hearing screening and had (1) one ear refer near birth, (2) one ear pass near birth, and (3) both ears demonstrate normal thresholds through a detailed hearing assessment about 1 month later. Since both ears had normal hearing at about 1 month old, it is assumed that the referral at birth resulted from transient debris or fluid in the middle ear (the ear canal was visually confirmed to be clean). Reflectance measurements on this population of ears provide comparisons between three conditions:

1. Reflectance measures within 2 days of birth on a subject with one normal ear and one ear with debris or fluid allows analysis of how the fluid or debris affect the reflectance;
2. Reflectance measures within 2 days of birth and at about 1 month old on the ear that was normal at both times allows analysis of how reflectance changes during the first month of life; and
3. Reflectance measures at age about 1 month on the 2 normal ears, one of which referred near birth, allow analysis of how fluid or debris at birth affects the reflectance when the fluid or debris dissipates before 1 month old.

MATERIALS AND METHODS

The study was approved by the Institutional Review Boards at the Massachusetts Eye and Ear Infirmary, the Massachusetts General Hospital, and Smith College. Written consent was obtained from parents of the subjects.

Overview of Procedure

The parents of full-term healthy babies born at the Massachusetts General Hospital (December 2008 to April 2011) were asked if their child would participate in this study if the child had a unilateral refer on his or her ABR-based newborn hearing screening (Herrmann et al. 1995, ALGO 3 and 3i Infant Hearing Screener, Natus Inc.), which was done by Massachusetts Eye and Ear Infirmary audiology screening technicians or audiologists within 2 days of birth. Upon referral, the child was also scheduled for a full diagnostic ABR hearing evaluation at the Massachusetts Eye and Ear Infirmary's Audiology Department at about 1 month of age to determine hearing status in detail. This full hearing evaluation included measuring air and bone conduction thresholds for tonebursts of different center frequencies in each ear and was identical to the clinical assessment provided for all infant hearing assessments done at this hospital.

The initial ABR screening at birth and study-specific measurements were performed by different staff members. After an ABR unilateral refer during screening was identified, an audiologist associated with the study was alerted, and there were time differences of up to several hours between the initial ABR screening and the study-specific measurements. Within these several hours, it was possible for fluid or debris within the ear to clear or be reduced. To control for that possibility, the measurements associated with this study included both DPOAEs and reflectance measures made with the Mimosa HearID system made within a few minutes of one another (detailed below). A retrospective analysis showed that 4 subjects passed the later, near birth DPOAE screening, and those subjects were no longer considered a unilateral refer for the analyses presented here.

Subject Inclusion Criteria

The subject inclusion criteria were (1) parental consent, (2) unilateral refer at birth based on initial ABR screening and DPOAE screening associated with study measurements, and (3) both ears passed a diagnostic ABR evaluation at age 1 month. A total of 46 newborn babies (defined as 0 to 2 days old) who had a unilateral refer on their ABR screening were enrolled in the study and one was withdrawn before measurements were taken. Of the remaining 45 babies, reflectance and DPOAE measurements were made on 45 newborn babies, and follow-up reflectance and DPOAE measurements were made on 38 of these same babies during their first month of life (range 14 to 35 days); 7 subjects did not have follow-up measurements made on them either because they passed a screening at a later time or they did not have reflectance measurements made at their follow-up appointment. Within this cohort of 38 subjects, at the time of the follow-up evaluation, 3 subjects had a mild conductive loss and 1 had a sensory neural loss (all unilateral). The remaining 34 subjects had bilateral normal hearing at the follow-up evaluation. As described above, 4 of these subjects passed the DPOAE screening as a newborn at the time of study enrollment and were thus eliminated as a true unilateral refer. Thus, a full set of measurements was made on a total of 30 subjects who met the subject inclusion criteria listed above.

Measurement System for Reflectance and DPOAEs

Measurements of reflectance and DPOAEs were made with an Etymotic ER-10c probe using software and hardware developed by Mimosa Acoustics (HearID v4.4.100; Hunter et al. 2010; Merchant et al. 2010). The details closely follow those reported by Merchant et al. In brief, the Thévenin equivalent and the ear-canal pressure were measured on both of the two channels within the ER-10c probe. The ear-canal pressure measurement was in response to a wideband chirp stimulus at 70 dB SPL, and the average of 235 measurements is reported (FFT length of 2048, a sampling rate of 48 kHz, and a frequency resolution of about 25 Hz). Measurements of the ear-canal pressure were combined with the probe's Thévenin equivalent to calculate the power reflectance within the ear canal, as described elsewhere (e.g., Merchant et al. 2010); these calculations were done within the software package Matlab (version 7.12). The measured pressure responses were smoothed with a seven-point moving average filter. To minimize acoustic leaks, foam tips (size 14 B, Etymotic Research) were trimmed with scissors to allow them to fit into newborn ear canals; the rubber tips that are commercially available for the Etymotic ER-10c did not stay seated as well in the newborn ear canals (e.g., Merchant et al. 2010). The diameter of the expanded foam tip, after being thinned out, was estimated at 4.0 mm, which is the value used for the reflectance measure calculations.

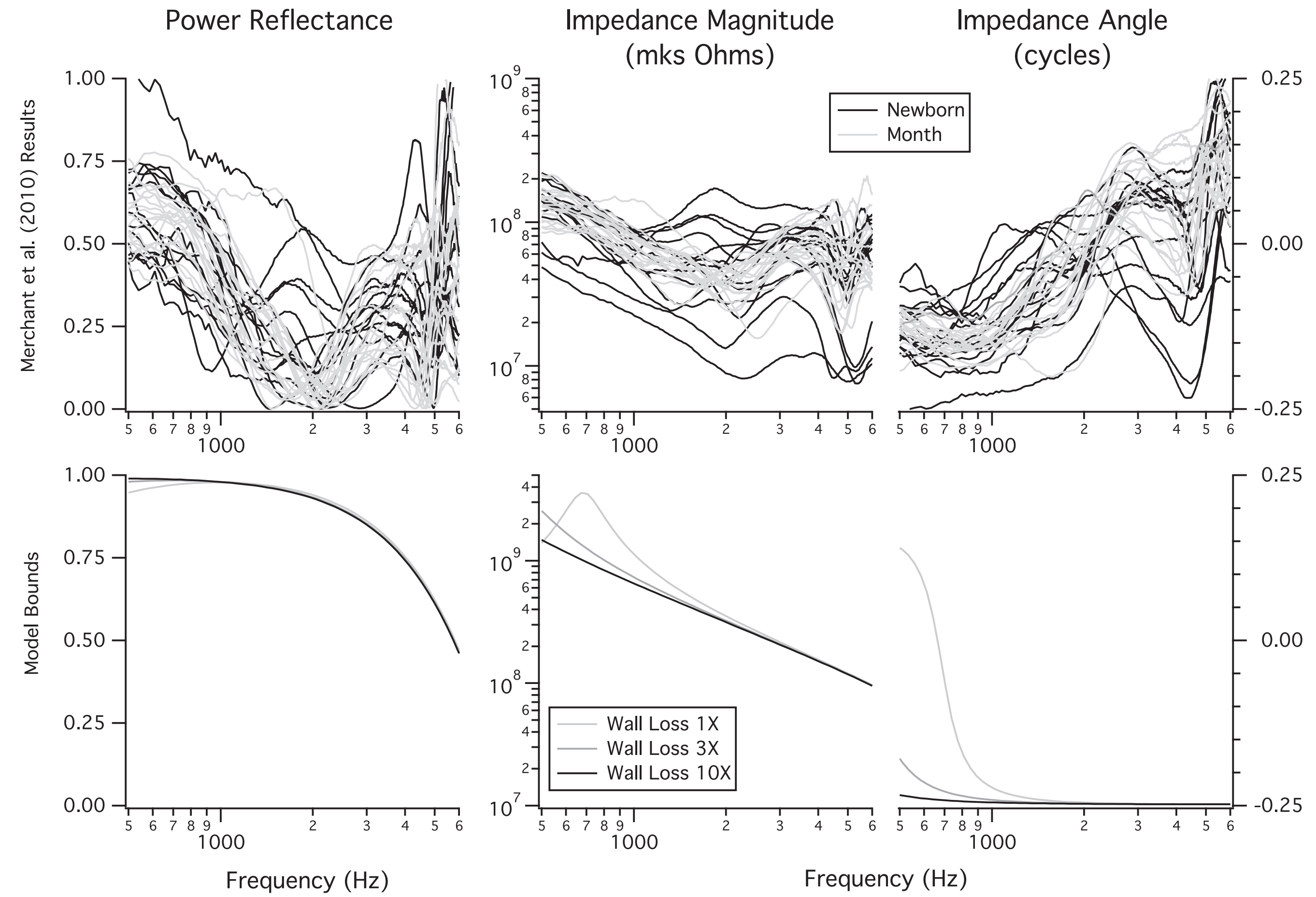

Fig. 1. Power reflectance (*left*), impedance magnitude (*center*), and impedance angle (*right*). *Upper* Data from Merchant et al. (2010) from 15 newborn (3–5 days) ears (*black lines*) and 19 month-old (28–34 days) ears (*gray lines*). *Lower* Model predictions for an entirely fluid-filled ear, based on rigid termination of the ear canal and values described in the text.

DPOAEs were measured at $f_2/f_1 = 1.2$, $L_1 = 65, L_2 = 55$, for the four f_2 frequencies of 2, 3, 4, and 6 kHz; when the DPOAE signal exceeded the noise floor by 6 dB at three of these four frequencies then the ear was considered to "pass" a DPOAE screening. These criteria are similar to those used by Sanford and Feeney (2008) and Hunter et al. (2010).

Data Selection Criteria

Merchant et al. (2010) found that reflectance measurements in young babies are particularly sensitive to the quality of the acoustic seal, occlusion of the probe tip due to contact with the ear-canal wall, and the fussiness of the baby. To assess the quality of measurements taken for the work presented here, a set of criteria based on impedance angle, impedance magnitude, and power reflectance was developed for infant ears. We refer to these as the "data selection criteria" (DSC). We base these criteria on the measurements plotted in Figure 1 from Merchant et al. and some modeling predictions described below.

Figure 1 (upper) puts bounds on how the power reflectance and impedance magnitudes and angles behave in normal hearing newborn and month-old ears. Important features include (1) the power reflectance has a relatively higher value at the lowest frequencies and generally decreases smoothly with frequency for some range within 500 to 2000 Hz; (2) the impedance magnitude is always below 3×10^8 mks Ohms; and (3) below about 1 kHz, the impedance angle is bounded between −0.25 and 0 cycles and is relatively flat or gradually increases with frequency. These features are what define the DSC (Table 1) for the normal ears in our population. As more measurements are made in the future and the acoustical responses of younger ears are better understood, we expect the DSC to evolve.

Fewer measurements exist on ears that refer for transient middle ear conditions (e.g., typically middle ear fluid). Here, we use acoustical theory to put bounds on the impedance magnitude and angle for such ears. First, we consider the largest impedance magnitude we might expect to measure on an ear fully filled with fluid. Here, we assume a tube for the ear canal and a rigid termination representing an immobile tympanic membrane. Our bounds should include as small a volume as practical for an infant's ear canal, and we choose a diameter of 0.3 cm and a length of 0.5 cm. This model should also include realistic ear-canal walls, which include losses, and we use the ear-canal model from Voss et al. (2008) that employed measurements from the vocal track wall from Stevens (1998). Figure 1 (lower) shows model estimates for this fluid-filled ear with ear-canal-wall impedance equivalent to 1, 3, and 10 times that of the vocal tract; as further described by Voss et al., the ear-canal wall impedance is probably greater than that of the vocal track; current knowledge does not permit comparison of the infant ear-canal wall impedance to that of the measured vocal tract. Here,

TABLE 1. DSC categorized by measurement type and ear status

Measure	Ear Status	DSC
Reflectance	Normal ears	Decreases systematically as frequency increases for some frequency range within about 500–2000 Hz
Impedance magnitude	Referred ears	Less than 10^9 mks below 1 kHz
	Normal ears	Less than 5×10^8 mks below 1 kHz
Impedance angle	All ears	Bounded between −0.25 and 0 cycles over the majority of low frequencies (i.e., below 1 kHz)
	Normal ears	Relatively flat or gradually increasing with frequency below 1 kHz
All measures	All ears	Do not rapidly change with frequency
	All ears	If two channels are similar and both channels meet the above DSC, then choose channel 2
	All ears	If two channels differ and one channel meets the above DSC, then use that channel
	All ears	If two channels differ and both channels meet the above DSC, then reject the measurement

"All ears" refer to both normal and referred ears.
DSC, data selection criteria.

we use these values simply for a bound. The model predictions in Figure 1 (lower) are summarized as part of the DSC for the ears that refer at birth; again, we expect these to evolve as more measurements are made on live ears.

One final DSC involves which of two measurements is reported for a given ear. The HearID system uses the ER-10c earphone with two speakers, the Thévenin equivalent is determined for each of the two channels, and two measurements are taken sequentially, one on each channel. In many cases, the measurements on the two channels are very similar, and we use the measurement from channel 2 in these cases as a matter of routine. There are, however, cases where the two channels are distinctly different; under these circumstances we either (1) use the one channel that meets the DSC in the cases where one channel meets the DSC and the other one does not, or (2) exclude the measurement if both channels meet the DSC but are substantially different. Table 1 summarizes these criteria.

Figure 2 provides four examples of the application of the DSC from Table 1. The left most plots from subject 39 show measurements made on channels 1 (thinner lines) and 2 (thicker lines) on both the right ear (red lines) and left ear (blue lines) within 2 days of birth (solid lines) and at 1 month (dashed lines). In this case, the left ear referred and the right ear passed the ABR screen. All eight of these measures met the DSC and channel 2 was used in the data analyses by default. The left-middle plots show that the measurements from the left ear of subject 7 within 2 days of birth meet the DSC on only channel 2 and not channel 1; thus, data on channel 2 is used for further analysis. This left ear passed its newborn hearing screening. It is hypothesized that measurements such as the one on channel 1 here might be affected by an acoustic leak since the impedance magnitude is relatively low, consistent with a large volume, and the measure itself appears affected by noise. The middle-right plot provides an example in which the DSC were not met for either channel (subject 29's right ear at follow-up); on both channels, the impedance magnitudes were larger than the required range for a normal ear. This ear passed an ABR hearing test at follow-up. It is hypothesized that the probe tip was up against the ear canal in cases such as this, resulting in measuring the response of a volume of air instead of the ear drum. The right-most plots are measurements from subject 25 at birth from the left ear, which referred. Both channels meet the DSC, but the measurements differ substantially on the two channels; as a result these data are rejected.

Data Analysis

As detailed above, measurements were made on 30 subjects who had a newborn hearing screening with a unilateral pass (one ear pass and one ear refer) followed by a month-old hearing assessment that determined normal hearing in both ears. From these measurements, we present three comparisons:

1. *Association of ear's state with power reflectance at birth*: In this case, we compare subjects with valid measurements (meet all DSC) within 2 days of birth for both the ear that passed and the ear that referred to quantify the effect of the transient middle ear condition on the power reflectance. Within the 30 subjects, measurements on both ears near birth (referred and passed) met the DSC for 15 subjects. All measurements were made between 0 and 2 days old.
2. *Age comparison: Changes in power reflectance of normal ears between newborn and 1 month old:* In this case, we compare power reflectance of the ear that passed near birth to the measurements made near birth and at 1 month to quantify how the power reflectance may or may not change over the first month of life. Within the 30 subjects, these measurements met the DSC for measurements made both near birth and 1 month for 19 subjects; all newborn measurements were made within 0 and 2 days old, and all month-old measurements were made between 17 and 35 days old (median 23 days, mean 23.5 days).
3. *Association of ear's newborn state with ear's power reflectance at 1 month:* In this case, we compare the power reflectance of the 2 ears at age 1 month to determine if the state of the ear at birth affects the power reflectance at age 1 month. Within the 30 subjects, the measurements made on both ears at age 1 month met the DSC for 17 subjects. All measurements were made between 14 and 35 days old (median 24 days, mean 23.5 days).

Statistical Analysis

Comparisons between two groups of ears were made using a paired t test with the Matlab function "ttest" (Matlab version 7.12.0.635). This function was used to perform a paired t test of the hypothesis that paired measurements came from

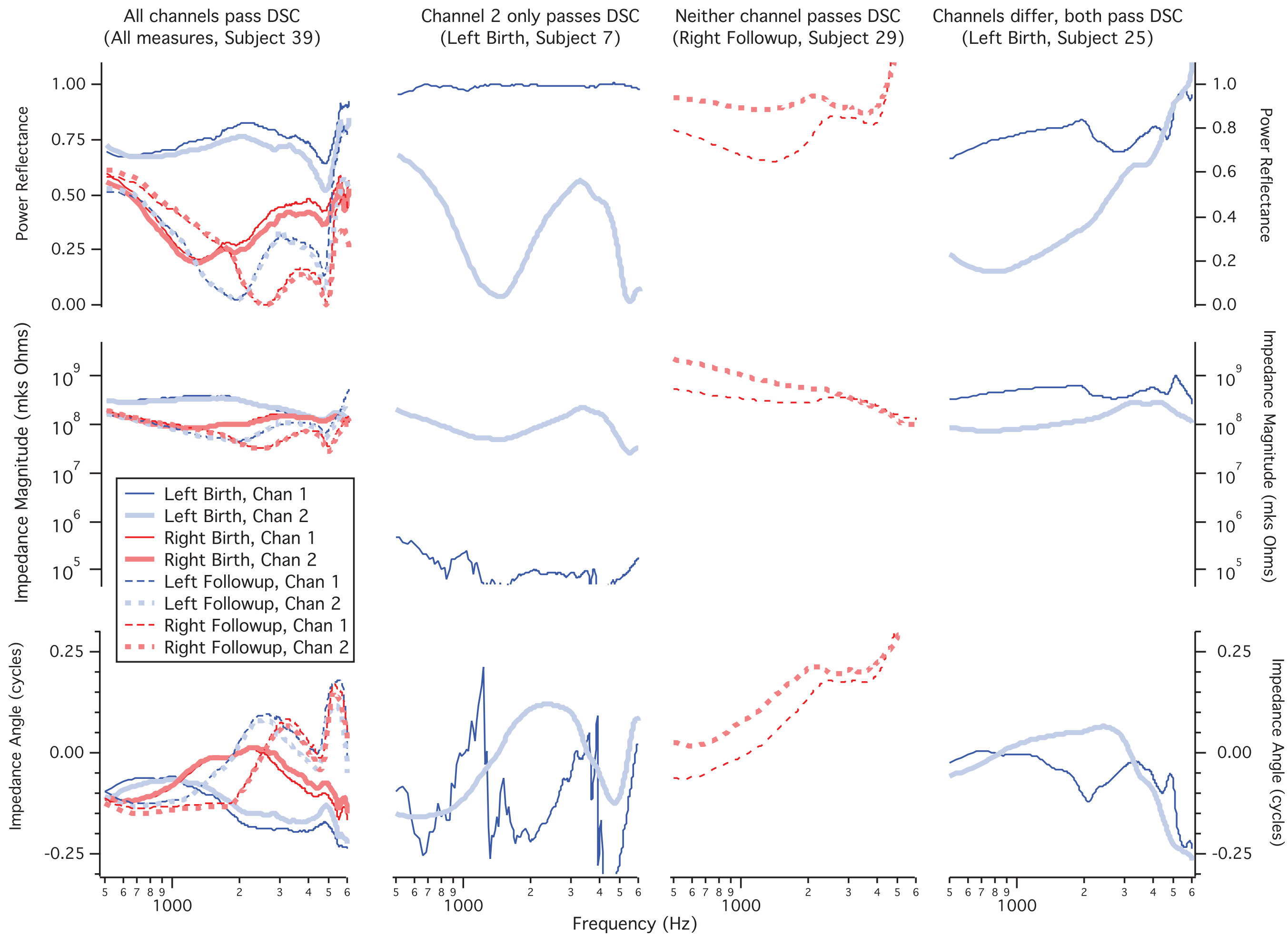

Fig. 2. Examples to illustrate the application of the data selection criteria from Table 1. Data from 4 subjects are presented, specifically, power reflectance (*upper plots*), impedance magnitude (*middle plots*), and impedance angle (*lower plots*). *Left* All 8 measurements from subject 39 meet the DSC and are similar on both channels. Thus all of this data is accepted and channel 2 is used for further analysis. *Left-middle* The measurements from the left ear of subject 7 within 2 days of birth meet the DSC on only channel 2 and not channel 1; thus, data on channel 2 is used for further analysis. This left ear passed its newborn hearing screening. It is hypothesized that measurements such as the one on channel 1 here might be affected by an acoustic leak since the impedance magnitude is relatively low, consistent with a large volume, and the measure itself appears affected by noise. *Middle-right* The DSC were not met for either channel from subject 29's right ear at follow-up; on both channels, the impedance magnitudes were larger than the required range for a normal ear. This ear passed an ABR hearing test. It is hypothesized that the probe tip was up against the ear canal in cases such as this, resulting in measuring the response of a volume of air instead of the eardrum. *Right* Measurements from subject 25 at birth from the left ear, which referred. Both channels meet the DSC, but the measurements differ on the two channels; as a result, these data are rejected. DSC indicates data selection criteria.

distributions with equal means. The test output includes a 95% confidence interval for the true mean of the difference between the states and was calculated with a significance level alpha of 0.05, indicating the probability of observing a difference outside of the 95% confidence interval by chance is less than 5%, given that the distributions have equal means. No corrections were made for multiple comparisons across frequency.

RESULTS

Association of Ear's State on Power Reflectance Near Birth

Figure 3 compares the power reflectance, impedance magnitude, and impedance angle measured near birth on the 15 subjects with one ear that passed the ABR newborn hearing screening and one ear that referred and was found to have normal hearing at 1 month old. All 15 datasets that meet the DSC for measurements made near birth are displayed, as these are the only data that directly compare this condition within a group of subjects with a control ear (i.e., normal-hearing ear).

The trends in the data are generally systematic. In 13 of the 15 ears, the low-frequency power reflectance (below 1000 Hz) is higher in the referred ear (ear with transient middle ear conditions) as compared with the normal ear. Ears from subjects 11 and 20 do not follow this trend. The power reflectance from subject 11 appears similar for both ears, and the power reflectance from subject 20 decreases with decreasing frequency so that at the lower frequencies (200 to 500 Hz) the power reflectance of the referred ear is lower than that of the ear that passed.

The impedance magnitude is larger in all of the referred ears up to about 2000 Hz and across the entire frequency range of 200 to 6000 Hz in some of the ears. The angle of the impedance is less systematic between the two ear conditions. In some cases, the low-frequency angle is larger in the referred ears than in the ears that passed, but the opposite situation is also common.

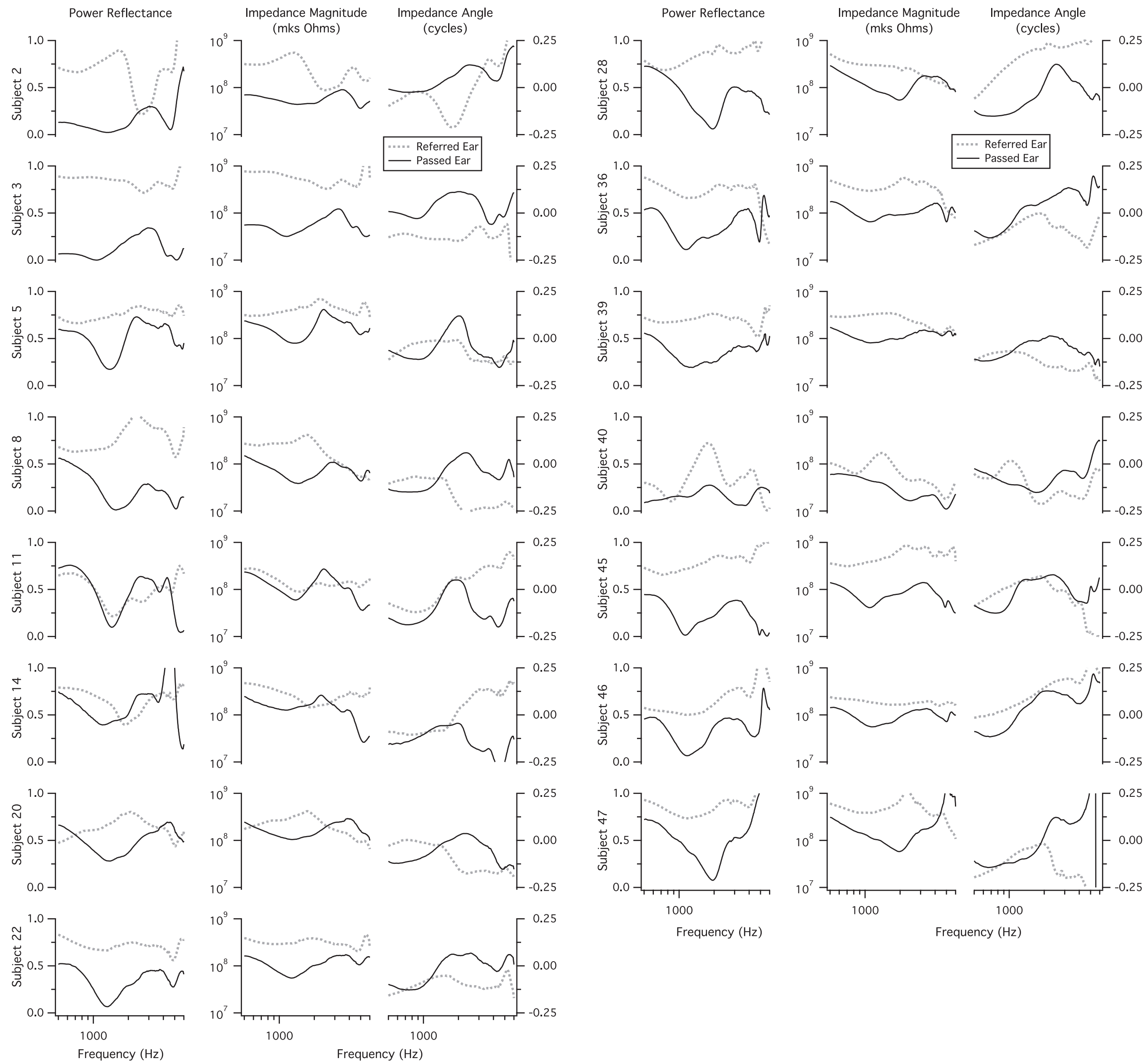

Fig. 3. Power reflectance and impedance magnitude and angle measured near birth on 15 subjects in which 1 ear passed and 1 ear referred on the newborn hearing screening. For each subject, the *left column* is the power reflectance, the *middle column* is the impedance magnitude, and the *right column* is the impedance angle. *Solid black lines* are measurements made near birth on the ear that passed the newborn hearing screening, and measurements in the *dashed gray lines* are those made on the ear that referred at the newborn hearing screening.

Figure 4 (left column) plots the means and 25% to 75% ranges of the power reflectance from the newborn ears that both passed and referred. The power reflectance is systematically larger in the ears that referred, and the 95% confidence interval of the difference between the two groups does not include zero, suggesting that the difference is statistically significant at all frequencies.

Age Comparison: Changes in Power Reflectance of Normal Ears Between Birth and 1 Month Old

Figure 5 compares the power reflectance, impedance magnitude, and impedance angle measured near birth and 1 month on 19 ears that passed a hearing screening near birth and a full ABR hearing evaluation at 1 month old (including bone conduction and threshold testing). All 19 datasets are displayed, as these are the only data that directly compare measurements on the same ear at these 2 specific ages.

In roughly half—9 of the 19 ears—the measurements appear similar at the 2 measurement times of near birth and 1 month old, specifically those measurements from subjects 1, 4, 5, 7, 8, 11, 23, 28, and 46. Some of these ears have more similar measurements than others, but in these 9 cases, the 2 measurements are arguably similar in terms of relative values and frequencies at which extrema occur.

In the remaining 10 ears, there are larger differences between the measurements made near birth and at 1 month; specifically those measurements from subjects 3, 12, 13, 14,

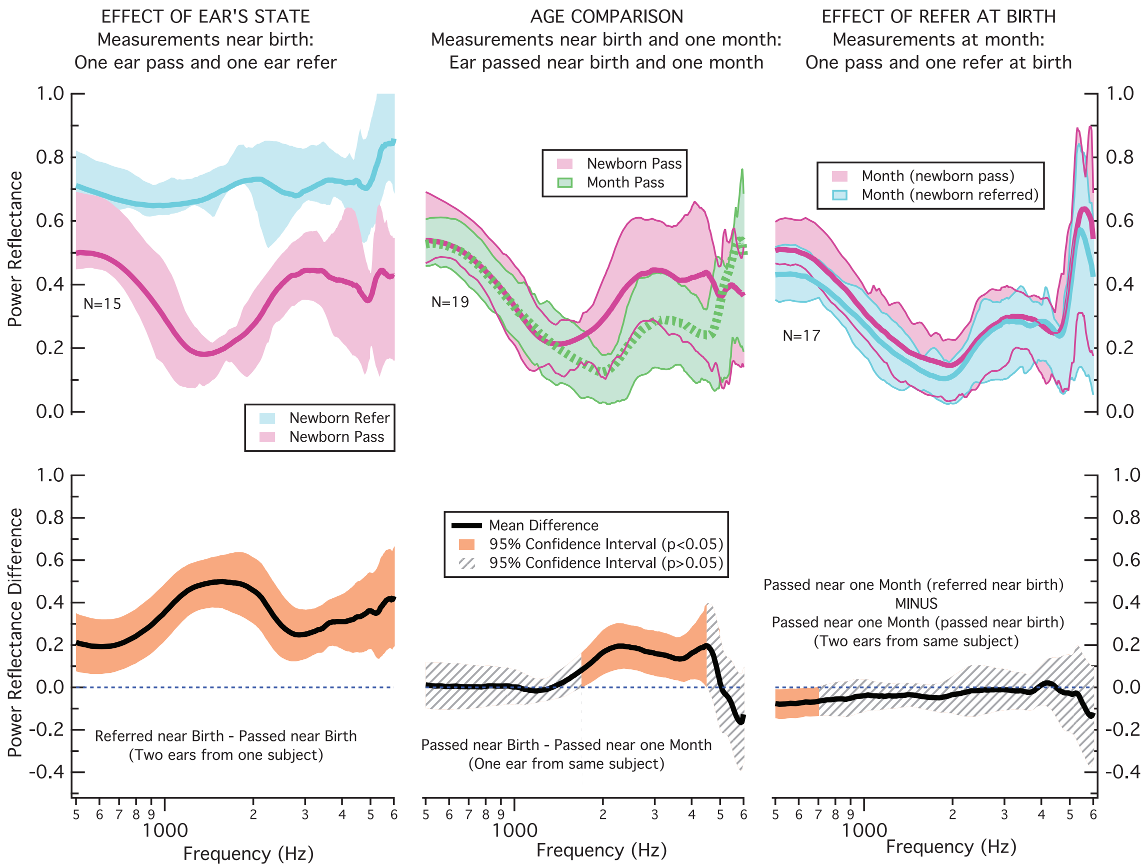

Fig. 4. Power reflectance comparisons between ears that passed and referred at the newborn screening. *Solid lines* are means and *shaded regions* include the 25% to 75% range for the data. *Left* Effect of ear's state near birth (refer vs. pass) on power reflectance near birth. *Left-upper* Power reflectance measured near birth on the ear that referred (*cyan*) and the ear that passed (*pink*). *Left-lower* Mean difference between the ears that referred and passed (*black*) and the corresponding 95% confidence interval (*shaded orange*) for the difference ($p < 0.05$). *Middle* Effect of age (birth or 1 month) on ears that passed near birth. *Middle-upper* Power reflectance measured near birth (*pink*) and at 1 month (*green*) on ears that passed hearing screening at both birth and 1 month. *Middle-lower* Mean difference between the power reflectance near birth and 1 month (*black*) and the corresponding 95% confidence interval, which is *shaded orange* at frequencies where it does not include zero and *hashed* when it includes zero. *Right* Effect of ear's state near birth (refer vs. pass) on power reflectance at 1 month. *Right-upper* Power reflectance measured at 1 month on the ear that referred near birth (*cyan*) and the ear that passed near birth (*pink*). *Right-lower* Mean difference between the power reflectance at 1 month on the ear that had referred near birth and passed near birth (*black*) and corresponding 95% confidence interval, which is *shaded orange* at frequencies where it does not include zero and *hashed* when it includes zero.

20, 36, 38, 39, 40, and 47. In some cases, the measurements are similar for part of the frequency range but deviate for substantial frequency ranges as well. Among these ears, at most frequencies, the power reflectance is lower at age 1 month than it was near birth.

Figure 4 (middle column) plots the means and 25% to 75% ranges of the power reflectance from the measurements made on the ears that passed at both the newborn and 1 month ages. The power reflectance is systematically larger in the newborn ears from approximately 2000 to 5000 Hz, and the 95% confidence interval of the difference between the 2 ages does not include 0, suggesting that the difference is statistically significant at these frequencies.

Association of Ear's Newborn State With Ear's Power Reflectance at 1 Month

Figure 6 compares the power reflectance, impedance magnitude, and impedance angle measured at 1 month on both ears of 17 subjects; in this case, the measurement at the age of 1 month is compared between the two ears of the subject, where one of the ears passed a newborn hearing screening near birth and the other ear referred near birth. At age 1 month, both ears passed the hearing assessment.

At age 1 month, the two ears from a single subject appear similar in most of the 17 cases. Arguably, the power reflectance from subjects 40, 46, and 47 appear qualitatively different between the 2 ears, but generally the power reflectance and impedance angles and magnitudes from a given ear appear to have similar trends for any given subject.

Figure 4 (right column) plots the means and 25% to 75% ranges of the power reflectance from the measurements made on the subjects with 2 ears that passed at 1 month but had one ear refer near birth and one ear pass near birth. At 1 month old, the power reflectance does not depend on the state of the ear near birth above 700 Hz, and there is a suggestion that below 700 Hz the power reflectance of the ear that referred near birth could be slightly lower than that of the ear that passed near birth.

DISCUSSION

Data Selection Criteria

There are several issues that can theoretically cause poor quality measurements of impedance, power reflectance, and

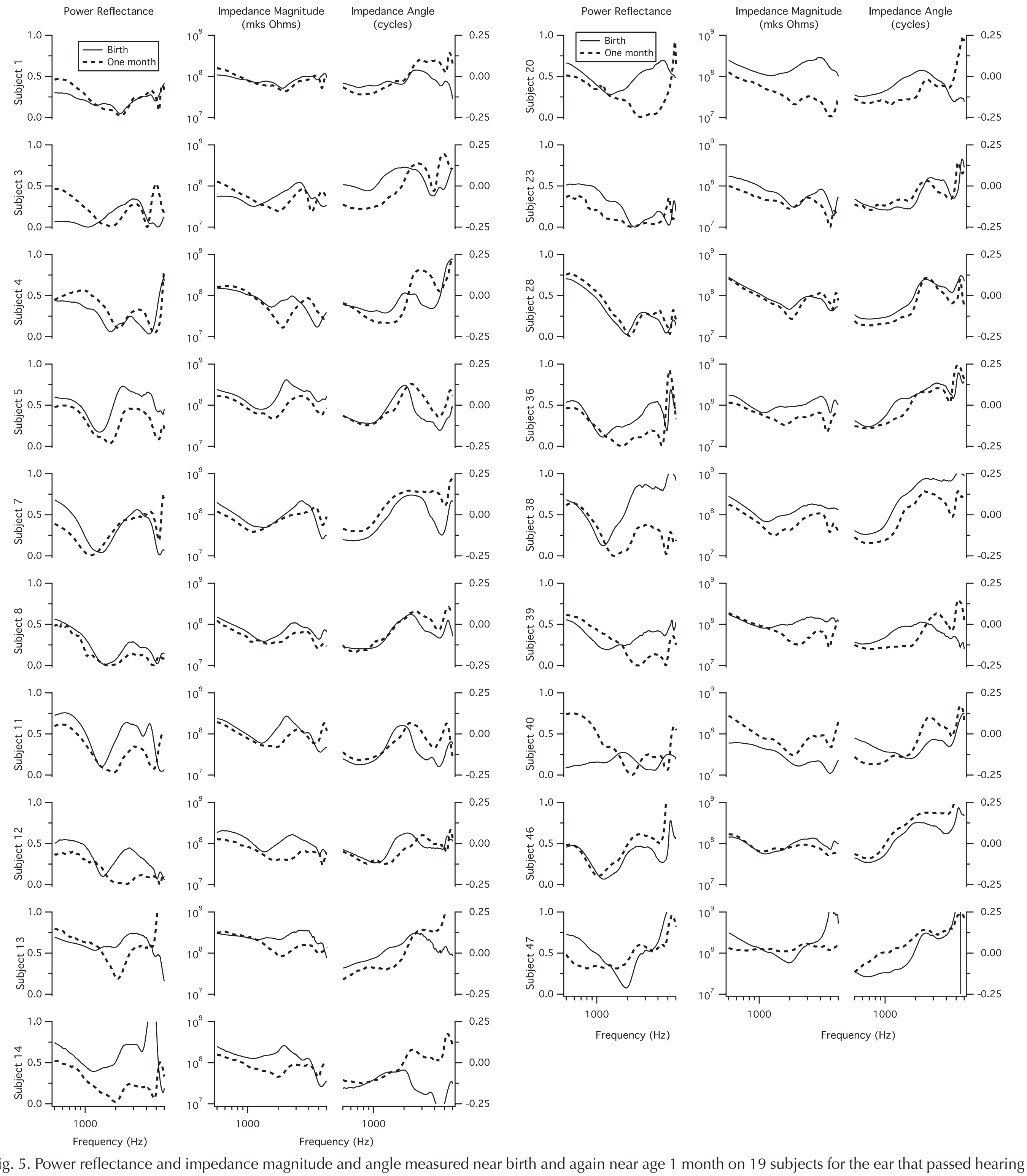

Fig. 5. Power reflectance and impedance magnitude and angle measured near birth and again near age 1 month on 19 subjects for the ear that passed hearing screening at both ages. For each subject, the *left column* is the power reflectance, the *middle column* is the impedance magnitude, and the *right column* is the impedance angle. *Solid lines* are measurements made near birth and *dashed lines* are those made near 1 month old.

related measures, including a microphone or sound source probe wedged against the side of the ear canal or inserted into a collapsed ear canal, a blocked probe (fluid or solid material), or an acoustic leak that results from a poor seal between the earphone and the ear canal. It is well known that obtaining a high-quality acoustic seal within the ear canal can be difficult in newborn ears (e.g., Keefe et al. 2000; Vander Werff et al. 2007; Hunter et al. 2008; Merchant et al. 2010). Within the “Materials and Methods” section, we proposed a preliminary set of DSC (Table 1) to help determine when an adequate seal exists and when measurements should be considered inadequate and eliminated or retaken. These proposed DSC are preliminary and based on the

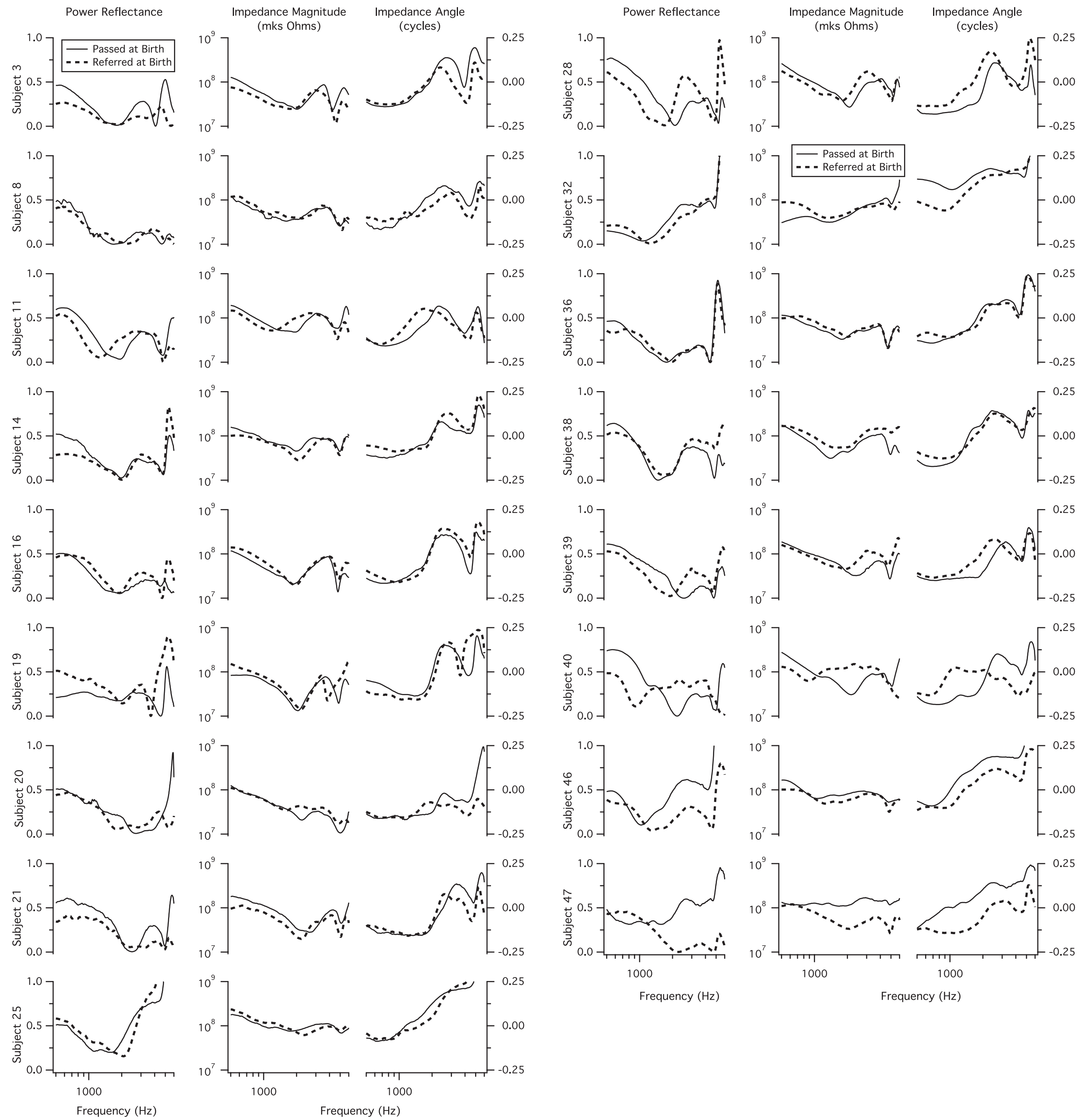

Fig. 6. Power reflectance and impedance magnitude and angle measured at 1 month old on 17 subjects with both ears passing a hearing screening at 1 month; *solid lines* are measurements on the ear that passed a hearing screening near birth, and *dashed lines* are measurements made on the ear that referred at the newborn hearing screening. At 1 month, both ears passed a full hearing evaluation. For each subject, the *left column* is the power reflectance, the *middle column* is the impedance magnitude, and the *right column* is the impedance angle.

relatively small dataset of measurements that exists in this work and the literature. The DSC for a normal-hearing newborn ear are based on multiple publications, but the DSC for a newborn ear with transient conductive loss likely caused by fluid are less well defined due to the paucity of such data. The study presented here is a first step in determining appropriate DSC, but it is not clear how the impedance angle and magnitude behave with abnormalities, such as fluid or debris associated with the transient middle ear conditions that are the subject of this study. The individual impedance and reflectance data presented in this study add to the available data in the ongoing need to develop and define appropriate DSC.

These preliminary DSC were designed to be conservative and to not eliminate any data that are potentially valid. Even so, we can identify individual measurements that are outliers and may be affected by acoustic leaks or other measurement problems.

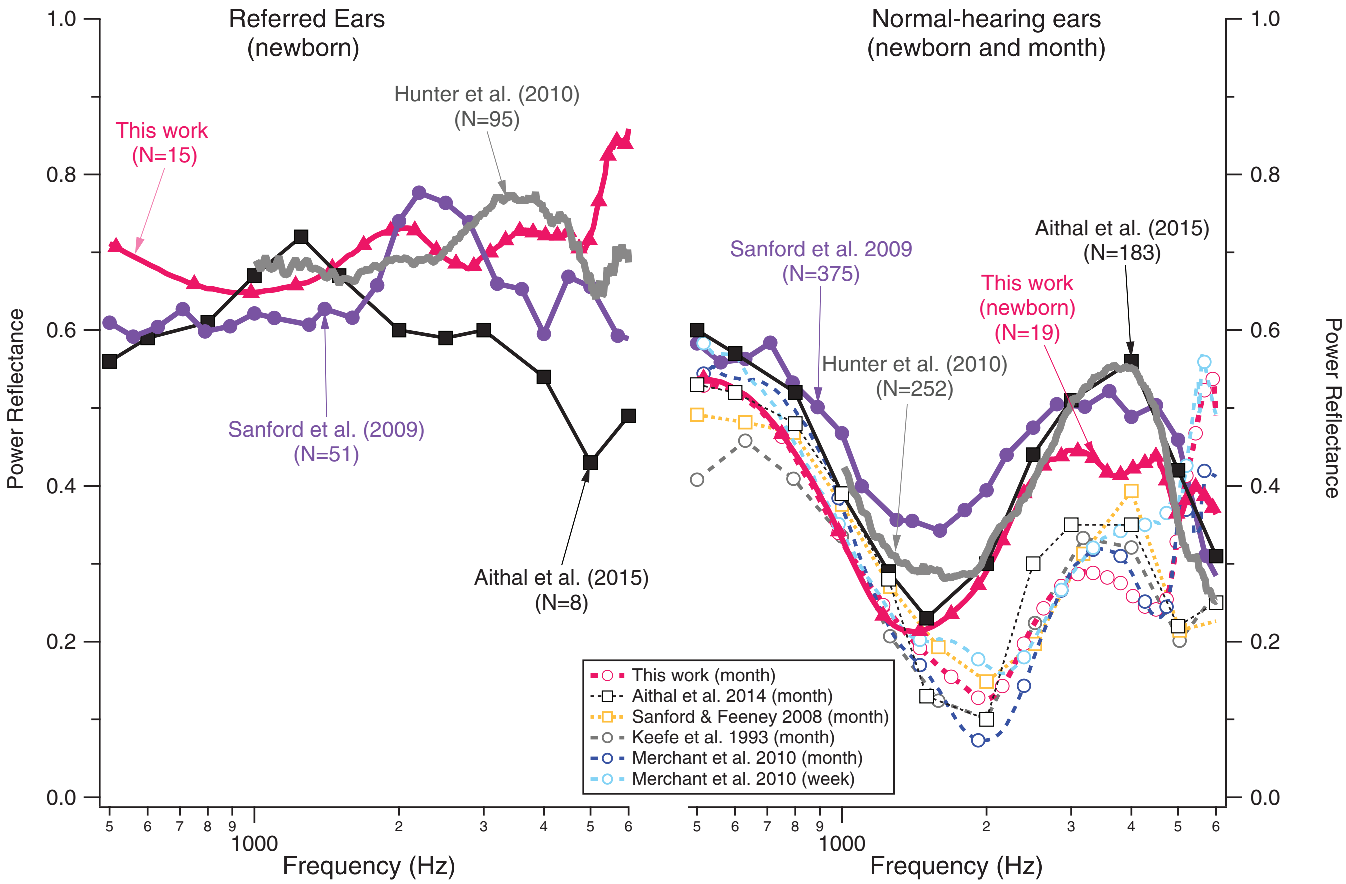

Fig. 7. Power reflectance comparisons between the study reported here (present study) and comparable studies reported in the literature. Scanning left-to-right one can compare reflectance measurements from ears that referred at birth (*left*) to ears that passed at birth (*right solid lines*) to normal hearing ears at 1 month (*right dashed lines*). *Left* Power reflectance measurements made on newborn ears that referred at birth and are assumed to have conductive loss. Reflectances measured by Hunter et al. (2010) and Sanford et al. (2009) were from ears that referred on DPOAE screenings, whereas those from Aithal et al. (2015) referred on ABR, DPOAE, and TEOAE screenings. The "present study" measurements are from ears that referred at birth on both ABR and DPOAE screenings and are the only dataset that was confirmed to have normal hearing at 1 month and thus confirmed to have conductive loss at birth. Measurements by Hunter et al. and the present study were made with the Mimosa system and measurements by Sanford et al. and Aithal et al. were made by similar systems that are now marketed by Interacoustics. *Right* Power reflectance measurements made on newborn, 1-week, and 1-month-old ears that were assumed to have normal hearing at the time of measurement. Specifically, DPOAE screenings were passed for measurements made on ears by Aithal et al. (2015, 2014), Hunter et al., Merchant et al. (2010), Sanford et al., Sanford and Feeney (2008), and the present study. In addition, ABR measurements demonstrated normal hearing in the ears reported as normal by the present study and Aithal et al. The data from "this study" shows the power reflectance from the same set of ears at birth and 1 month; thus they are both plotted in *red*. All other data at the two ages are from different populations. ABR indicates auditory brainstem response; DPOAE, distortion product otoacoustic emission.

For example, two of the newborn ears in Figure 3 (e.g., subject 20 referred ear and subject 3 passed ear) exhibit low-frequency impedance angle measurements that are nearly zero but remain negative and flat and corresponding impedance magnitudes that increase or remain constant with frequency; these features are not consistent with the typical compliant-dominated impedance measurement that is commonly observed at the lower frequencies. Future study might identify measurements that push the boundaries of the DSC, make multiple measurements on such ears, and determine which features result from poor acoustic seals and which features are to be expected as possible valid measurements.

Association of Ear's State on Power Reflectance Near Birth

Power reflectance near birth is systematically higher in ears that did not pass the newborn hearing screening as compared with ears that did pass (Fig. 4). This finding is consistent with the results of Sanford et al. (2009) and Hunter et al. (2010), who both showed significant increases in reflectance when compared between two newborn groups with DPOAE screening results of refer and pass; Aithal et al. (2015) also showed significant increases in reflectance at birth between groups of newborn ears with DPOAE and ABR results of refer and pass.

Figure 7 (left) directly compares the measurements made here to other measurements in the literature on newborn ears that referred at birth and are presumed to have a conductive loss at birth. While the measures from all 4 studies show variations on the order of about 0.1 to 0.2 in power reflectance, as a whole the collection of power reflectances plotted in this left panel (from referred ears) are generally higher than those plotted in the right panel from ears that passed a hearing screening at birth, consistent with the finding that ears with conductive loss have increased power reflectance. The experimental designs for these four studies have important differences that are worth noting.

First, the conductive-loss assumption was confirmed for the data in the present study since the ear was tested again at age 1 month and determined to have normal hearing, whereas in the other three studies, the subjects simply referred on the DPOAE screening and it was never confirmed that the population consisted of only conductive-loss conditions. A second difference is that the population of referred ears in the present study was initially identified with an ABR screening (followed by DPOAE testing) and those in the Sanford et al. (2009) and Hunter et al. (2010) studies were identified with a DPOAE screening; in theory, the populations in the two studies could differ if ABR and DPOAE screening differ in their sensitivities to conductive loss; the results of Doyle et al. (1997) suggest that ABR and DPOAEs are both sensitive to transient conductive loss, and in that study it was not possible to perform significance testing to differentiate between the two methods. The population from Aithal et al. (2015) referred via ABR, TEOAE, and DPOAE testing. Third, different measurement equipment was used in these studies. Both the current study and the measurements from Hunter et al. employed the Mimosa Acoustics MEPA system, whereas the Sanford et al. and Aithal et al. used a version of what is now commercially available through Interacoustics as the Titan for their measurements; note, all comparisons in this study are made at ambient ear-canal conditions. There are no obvious trends in the results that depend on the screening protocol or the measurement equipment; the Aithal et al. data appear to be the least sensitive to the conductive-loss condition, but this may also be that there were only eight ears included in that dataset. A final difference among the measurements is that these four studies employed different approaches to select and then exclude data that could have been corrupted by acoustic leaks, ambient noise, and collapsed canals. In particular, the data from Hunter et al. and Aithal et al. appear to have been assessed for acoustic leaks using a visual method of looking at the reflectance (or absorbance) magnitudes only; additional considerations were made for ambient noise. Sanford et al. used a system that was automated to analyze the complex low-frequency response for a typical signature of a leak (increased resistance and mass components). This current study employed the "data selection criteria" proposed here to minimize effects of acoustic leaks on the reported data. Thus, it is possible that these four studies include data selection procedures that have different sensitivities to acoustic leaks.

Age Comparison: Changes in Power Reflectance of Normal Ears Between Birth and 1 Month Old

The middle column of Figure 4 compares reflectance measurements made on the same population of ears at the two ages of newborn and 1 month old; all ears passed the newborn hearing screening and had normal hearing at the 1-month hearing assessment. These data suggest changes in the acoustic behavior of the ear in approximately the 2000 to 5000 Hz range, with the power reflectance decreasing in this range over the first month of life. There do not appear to be systematic differences between the newborn and 1-month-old response at other frequencies.

Figure 7 (right) compares measurements made here to others in the literature of normal-hearing newborn and 1-month-old babies. Plotted are power reflectance measurements (1) made within 2 days of birth (solid lines) from this study and 3 published studies (Sanford et al. 2009; Hunter et al. 2010; Aithal et al. 2015), (2) made at about a week old (Merchant et al. 2010), and (3) made at about a month (dashed lines) from this study and 4 published studies (Keefe et al. 1993; Sanford & Feeney 2008; Merchant et al. 2010; Aithal et al. 2014). Differences among the four datasets collected at birth might be explained by similar circumstances that were discussed above for the differences among the referred ears, as these data were from the same experimental conditions for the respective authors. Taken collectively, all datasets measured at birth show systematic increases in power reflectance from all datasets taken at 1 month over the frequency range of approximately 2000 to 5000 Hz.

Among the datasets collected at age 1 month, the method of determining normal hearing varied. Keefe et al. (1993) assumed normal hearing based on behavior and parental interviews, Sanford and Feeney (2008), Merchant et al. (2010), and Aithal et al. (2014) screened for hearing loss via DPOAEs, and the current study employed diagnostic ABR testing. Also, different instruments were used to collect the reflectance measurements. The Mimosa Acoustics MEPA system was used by Merchant et al. and the current study, whereas a version of what is now marketed by Interacoustics as the Titan was used for the measurements reported by Keefe et al., Sanford and Feeney, and Aithal et al. Again, no trend is apparent that depends on the screening method or the measurement equipment.

One dataset exists that was measured on babies at 1 week old (Merchant et al. 2010; Fig. 7, right). These measurements at 1 week appear more similar to the measurements at 1 month than to the newborn measurements at 0 to 2 days. The differences are consistent with an observation by Keefe et al. (2000), which suggests over the first few days of life a subset of newborn ears has a relatively high reflectance that decreases over a few days. One hypothesis that would explain these observations would be that the middle ear of a newborn "dries out" over the first few days of life so that by age 1 week ears are usually dried out and the reflectance resembles that at age 1 month.

This observation that ears on the order of a few days old have higher reflectance than those at 1 week is also consistent with Hunter et al. (2010) who concluded (1) "Reflectance improved significantly during the first 4 days after birth with normalization of the middle ear function," and (2) "Newborns with high reflectance. . . should be rescreened within a few hours to a few days because most middle ear problems are transient and resolve spontaneously."

Association of Ear's Newborn State With Ear's Power Reflectance at 1 Month

Our experimental design—with measurements taken near birth on subjects with a unilateral refer and repeated at 1 month when normal hearing is measured in both ears—allows for comparison of reflectance measurements made at 1 month between ears from the same subject that passed near birth and referred near birth. The right column of Figure 4 compares these measurements and suggests that there are no differences, except possibly at the very lowest frequencies (less than 700 Hz). These results suggest that when newborn ears are affected by transient middle ear conditions and those conditions clear by age 1 month, the affected ear exhibits normal power reflectance at age 1 month.

Clinical Significance

This study contributes to a growing body of research that suggests that some newborn ears appear to exhibit a middle ear transient state, likely associated with fluid and other debris within the middle ear, that can be detected by a noninvasive wideband acoustic immittance measurement such as power reflectance. The study also suggests that the transient state typically resolves over the course of hours to several days (i.e., the newborn ear dries out). For some newborns, the state of the middle ear causes a shift in hearing threshold and a refer on the newborn hearing screening.

Based on similar findings to those reported here, some researchers have suggested that a reflectance measure could be used in conjunction with a newborn screening refer to add additional information to the status of the ear near birth, leading some to recommend a rescreen of that ear during the newborn period (e.g., Keefe et al. 2000; Sanford et al. 2009; Hunter et al. 2010). In some cases, a rescreening might make sense in that the ear would "dry out" and subsequently pass the screening. At the same time, there are additional issues to consider related to recommending a rescreening: (1) The inclusion of an additional test after the first newborn screening would increase the cost of screening programs, and (2) rescreening could increase the likelihood that a child with a marginal or slight hearing loss who referred on the first screen could pass on the second screen and not be identified (Dedhia et al. 2013).

This study also proposes a preliminary set of criteria for determining when reflectance measures on young babies are corrupted by acoustic leaks, probes against the ear canal, or other measurement problems. Specifically proposed are "DSC" that depend on the power reflectance, impedance magnitude, and impedance angle. Additional data collected in the future are needed to improve and test these proposed criteria.

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